This project is part of the EDCTP2 program supported by the European Union

A-055: Study to Evaluate H56:IC31 in Preventing Rate of TB Recurrence
NCT03512249

April 6, 2025

Cover Page: Statistical Analysis Plan

Title: A Phase 2, Double-blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of H56:IC31 in Reducing the rate of TB Disease Recurrence in HIV Negative Adults Successfully Treated for Drug-Susceptible Pulmonary Tuberculosis

Final Version 2.0 dated 15 Sep 2023

Statistical Analysis Plan

Trial ID:

POR A-055

Phase 2 Trial

Author: [redacted]
Principal Statistician
[redacted]

Signature page

The signatures below confirm that the signees have read, understood, and approved of the contents of the present statistical analysis plan.

[redacted] MSc., [redacted]

(Trial Statistician)

DocuSigned by:
[redacted]
Signer Name: [redacted]
Signing Reason: I approve this document
Signing Time: 15-Sep-2023 | 11:48 CEST
45CA3931FFAF475899145E1D2F824776

Signature and date

[redacted] MD, PhD, [redacted]

(Chief Medical Officer)

DocuSigned by:
[redacted]
Signer Name: [redacted]
Signing Reason: Jeg godkender dette dokument
Signing Time: 15-Sep-2023 | 12:01 CEST
332B1A8485D342DEB429E6FADEED561B

Signature and date

[redacted] MSc., PhD, [redacted]

(Section Manager)

DocuSigned by:
[redacted]
Signer Name: [redacted]
Signing Reason: Jeg godkender dette dokument
Signing Time: 18-Sep-2023 | 10:20 CEST
B202662BCCAC4D4999DA69082F6F6CAE

Signature and date

[redacted] MBChB, MSC medicine, [redacted]

(Medical Director)

DocuSigned by:
[redacted]
Signer Name: [redacted]
Signing Reason: I approve this document
Signing Time: 18-Sep-2023 | 12:27 CEST
EEB684EF613E4A9F953D81B10A61BEF8

Signature and date

Table of Contents

List of Abbreviations

AE	Adverse Event
AESI	Adverse Event of Special Interest
AFB	Acid Fast Bacilli
AR	Adverse Reaction
BMI	Body Mass Index
CI	Confidence Interval
CTR	Clinical Trial Report
DBL	Data Base Lock
eCRF	Electronic Case Report Form
ELISA	Enzyme Linked Immunosorbent Assay
ET	Early termination
GCP	Good Clinical Practice
H56:IC31	Fusion protein H56 (Ag85B, ESAT-6 and RV2660c antigens): IC31 adjuvant
HIV	Human Immunodeficiency Virus
IgG	Immunoglobulin G
ITT	Intention-To-Treat
MedDRA	Medical Dictionary for Regulatory Activities
mITT	Modified Intention-To-Treat
MLST	Multi Locus Sequence Typing
[redacted]	[redacted]
Mtb	Mycobacterium tuberculosis
N	Number of participants
PP	Per Protocol
PT	Preferred Term
SAE	Serious Adverse Event

SAP	Statistical Analysis Plan
[redacted]	[redacted]
SD	Standard Deviation
SNP	Single Nucleotide Polymorphism
SOC	System Organ Class
STB	Suspected Recurrent Tuberculosis
SUSAR	Suspected unexpected serious adverse reaction
TB	Tuberculosis
TEAE	Treatment Emergent Adverse Event
TC	Telephone Contact
WB ICS	Whole Blood Intracellular Cytokine Staining
WGS	Whole genome sequencing
WHO	World Health Organization
Xpert MTB/RIF (Ultra)	Cartridge based nucleic acid amplification test (NAAT), automated diagnostic test that can identify *Mycobacterium tuberculosis* (MTB) DNA and resistance to rifampicin (RIF)

1 Introduction

The statistical analysis plan (SAP) covers the trial, POR A-055, and is based on the final protocol version 5.0, dated 19 May 2021.

The SAP describes in detail the analyses to be conducted and highlights any deviations from the analyses described in the protocol (see section 9). Deviations from methods described in this SAP, if any, will be specified in the clinical trial report (CTR).

The following exploratory immunology endpoints are not within the scope of this SAP as they are described elsewhere: immunology or immunological correlates samples (immunoglobulin G (IgG) enzyme linked immunosorbent assay (ELISA), RNA analysis, blood subset count and ICS) taken at suspected recurrent tuberculosis (STB) visits, or as part of last follow-up for recurrent TB at a participant's last trial visit, as well as such samples taken at visit 8 (Day 421) for the exploratory immunology or immunological correlates analysis (see Appendix A, page 33). Furthermore, PBMC samples for ICS from all participants from visits 3 (Day 0) and visits 6 (Day 70), as well as the plasma samples for IgG ELISA from participants outside of the immunogenicity cohort from visits 3 (Day 0) and visits 6 (Day 70) are exploratory and are also not within the scope of this SAP.

Before releasing data for final analysis, one or more data review and classification meetings will be held to classify participants with respect to analysis populations. The product of the classification meetings will be a detailed description of the analysis populations, including reason for exclusion from the analysis sets for the individual participants.

The analyses will be performed based on:

- The clinical database, which includes the electronic Case Report Forms (eCRF) and laboratory data
- Analysis populations as documented at the classification meeting

Reporting of the trial will be after the date of last participant last visit.

2 Trial characteristics

2.1 Trial objectives and endpoints

2.1.1 Primary objective and endpoint

To evaluate the following in HIV-negative participants who have completed at least 5 months (22 weeks) treatment for drug-susceptible pulmonary tuberculosis (TB) and who test negative for acid fast bacilli (AFB) on sputum smear microscopy prior to vaccination (participants unable to produce sputum, and considered asymptomatic by the investigator, may be considered Mycobacterium tuberculosis (*Mtb*) negative):

- Efficacy of H56:IC31 compared to placebo in reducing the rate of recurrent TB disease (relapse or reinfection)

The primary objective will be assessed by the primary efficacy endpoint:

- Rate of TB disease recurrence (relapse or reinfection), defined as TB diagnosed by confirmation of *Mtb* by culture of sputum, during the period starting 14 days after the 2nd vaccination (V6= Day 70) and ending 12 months after the 2nd vaccination (V8= Day 421)

2.1.2 Secondary objectives and endpoints

To evaluate the following in HIV-negative participants who have completed at least 5 months (22 weeks) treatment for drug-susceptible pulmonary TB and who test negative for acid fast bacilli (AFB) on sputum smear microscopy prior to vaccination (participants unable to produce sputum, and considered asymptomatic by the investigator, may be considered *Mtb* negative):

Key secondary objective:

- Safety of H56:IC31 compared to placebo

The key secondary objective will be assessed by the key secondary endpoints:

- Solicited adverse events and all adverse events occurring the first 14 days after each of the 1st and 2nd vaccinations
- Serious adverse events including medically important events occurring after the 1st vaccination through the end of the trial

Other secondary objectives:

- Trends towards efficacy of H56:IC31 compared to placebo in reducing the rate of TB disease relapse
- Trends towards efficacy of H56:IC31 compared to placebo in reducing the rate of TB disease reinfection
- Antigen-specific cell-mediated immune responses to H56:IC31
- Humoral immune responses to H56:IC31

The secondary efficacy endpoints are the following:

- Rate of TB disease relapse, defined as a participant meeting the primary endpoint of TB disease recurrence, AND determined by whole genome sequencing (WGS) of the *Mtb* isolate to be the same strain of *Mtb* as in the participant's original isolate from the time of diagnosis, please see section 6.3 for a definition.
- Rate of TB disease reinfection, defined as a participant meeting the primary endpoint of TB disease recurrence, AND determined by WGS of the *Mtb* isolate to be a different strain than in the participant's original isolate from the time of diagnosis.
- Antigen specific cell mediated immune responses by whole blood intracellular cytokine staining (WB ICS) at baseline (V3= Day 0), and 14 days after the 2nd vaccination (V6= Day 70)
- Humoral immune responses by IgG ELISA of plasma samples taken at baseline (V3= Day 0) and 14 days after the 2nd vaccination (V6= Day 70)

Note, humoral immune responses by IgG ELISA of plasma samples taken at TB recurrence diagnosis (ET visit) are exploratory and not in scope of this SAP.

2.2 Trial Design

A-055 is a phase 2, double-blind, randomised, placebo-controlled trial. In total 900 participants are planned to be randomised 1:1 to one of the following treatment groups:

- H56:IC31
- Placebo

There are two sub-cohorts in the trial.

- The first 150 randomised participants are planned to be included in the Safety cohort subgroup.
- The first 100 randomised participants at the [redacted] and [redacted] sites are planned to be included in the Immunogenicity cohort subgroup, 50 participants from each site.

The safety cohort will be used to evaluate safety at the following planned timepoints:

- After 150 participants across all sites have received the 1st vaccination and 14 days of safety data following the 1st vaccination is available
- After all participants in the safety cohort have received the 2nd vaccination and 14 days of safety data following the 2nd vaccination is available, except for participants withdrawn before this timepoint.

Presentations of data solely linked to the interim safety cohort reviews are not covered by this SAP.

The immunogenicity cohort will be used for evaluation of the immunogenicity of the H56:IC31 vaccine by WB ICS and IgG ELISA of plasma measured at baseline, and 14 days after the 2nd vaccination.

2.2.1 Sample Size Considerations

The sample size for this trial was based on the following assumptions:

1. Estimated TB Disease Recurrence rate in placebo group: 4%/year.
2. Follow-up period for each participant: 12 Months post Day 70.
3. Drop-out/loss to follow-up rate: 10%.
4. Vaccine Efficacy (VE): 60%.
5. Type I error rate: 20% (2-sided).

Based on the above assumptions, a sample size of 900 participants (N=450 in each treatment arm) is expected to provide the 23 TB Disease Recurrence endpoints per active versus placebo comparison required to detect with 80% power a vaccine efficacy (VE) of 60%, assuming a 10% drop-out rate (i.e., 10% excluding participants who discontinue due to TB) and 12-month post Day 70 follow-up period for each participant.

3 Analysis Populations

The following 6 analysis sets are defined in the protocol and will be used in the analyses of the data:

- Safety analysis set: The safety analysis set will consist of all participants who received at least one dose of investigational product. Participants will be evaluated according to vaccination actually received. The safety analysis set will be used for evaluation of endpoints related to safety.
- Modified intention-to-treat (mITT) analysis set: The mITT will include all randomised participants except those with TB disease recurrence before Visit 6, Day 70 (or 14 days after the 2nd dose for those who received both vaccinations). Participants will be evaluated as randomised. The mITT is the primary analysis set for the primary and secondary efficacy endpoints.
- Second modified intention-to-treat (mITT2) analysis set: The mITT2 will include all randomised participants except those with TB disease recurrence prior to 30 days after the 1st dose. Participants will be evaluated as randomised. The mITT2 is the analysis set for the 3rd exploratory efficacy endpoint (section 6.5).
- Per protocol (PP) analysis set: The PP analysis set will consist of all participants who received both doses of H56:IC31 or placebo within the specified dose intervals, who entered the evaluation period for efficacy 14 days after receipt of the 2nd dose of H56:IC31 or placebo with no HIV seroconversion, and who had no major protocol deviation of clinical or statistical significance. Major protocol deviations are defined in Section 3.1. Participants will be evaluated according to vaccination actually received.
- ITT analysis set: The ITT analysis set will consist of all randomised participants. Participants will be evaluated as randomised.
- Immunogenicity analysis set: The immunogenicity analysis set will consist of participants from the mITT population who received both doses of H56:IC31 or placebo and who are included in the immunogenicity cohort. Participants will be evaluated as randomised.

Clarifications to the protocol definitions are below in *italic*:

- *Participants with a recurrence of TB exactly on day 14 after 2nd dose are excluded from the mITT and PP analysis set.*
- *Participants who only received 1st vaccination will be excluded from the mITT if they experience a TB recurrence before Visit 6 when the visit is in the visit window, i.e., on day 67-73, or else before day 70.*
- *Efficacy endpoints are presented in section 6 and safety endpoints in section 7*

The classification of the participants will be performed before database lock (DBL).

3.1 Major protocol deviations

Deviations from the protocol will be registered as protocol deviations with classification:

- Major
- Minor

and category

- Informed consent
- Eligibility criteria

- Withdrawal criteria not adhered to
- Dosing deviation
- Visit window
- Missed procedure(s)
- Specimen deviation
- Unblinding
- Safety reporting
- Other

Before DBL and unblinding, all protocol deviations will be evaluated. Protocol deviations classified as major can lead to exclusion from PP analysis set. The decisions will be documented in the DBL minutes.

The following will be assessed as major protocol deviations:

- Violation of inclusion criteria 5, 6 or 7
- Receipt of any investigational TB vaccine previously (excl. crit. 10)
- Receipt of any new investigational drug or investigational vaccine from Visit 1 through Visit 8 (excl. crit. 11)
- Receipt of any licensed vaccine from Visit 1 through Visit 6 (excl. crit. 12) except for SARS-Cov-2 vaccines recommended by national vaccination programs, which will be allowed if given > 28 days before and from the time of administration of clinical trial product.
- Receipt of treatment likely to modify the immune response (e.g., blood products, immunoglobulins, immunosuppressive treatment) within 42 days before Visit 3 through Visit 6. Inhaled and topical corticosteroids are permitted (excl. crit. 13)
- Received TB treatment (Rifampicin, Isoniazid, Pyrazinamide or Ethambutol) for current episode for more than 28 weeks
- Received the second vaccine outside visit window. The window was extended to two months after day 56 during the Covid-19 pandemic.
- Did not receive the 2nd vaccination
- Did not receive treatment as randomised
- HIV+ detection between Visit 3, Day 0 and Visit 6, Day 70 (14 days after the 2nd vaccination)
- Other protocol deviations which are assessed as having a clinically or statistically significant effect

Protocol deviations leading to exclusion from the PP analysis set will be summarised by treatment and in total. Number and percentages of participants will be presented, and percentages will be based on all randomised participants. Covid-19 related protocol deviations will be summarised by treatment, classification, (major/minor), and category. A similar summary of all protocol deviations will be made. Protocol deviations are rated into major or minor in the eCRF.

All protocol deviations will be listed by participant.

4 Planned Statistical Methods

4.1 Statistical Considerations

Baseline is defined as the last assessment with available data prior to the first vaccination. No statistical tests comparing treatment groups at baseline will be performed.

Categorical data will be summarised by treatment group, using number and percentages of participants. Continuous data will be presented using the number of participants (N), mean, standard deviation (SD), median, lower quartile, upper quartile, minimum and maximum. Both the absolute values and the change from baseline will be presented, if applicable. For calculation of percentages the denominator will be the number of participants in the analysis set, unless otherwise specified.

Descriptive statistics for all endpoints will be presented by treatment group and Visit (if applicable) using observed cases, i.e., no imputation of missing data will be performed. Missing data for time to event endpoints is handled using censoring.

All presentations will at least be by treatment group.

For summaries presented by visit, scheduled time will be used, and trial visits will be labeled as below:

Visit	Label
3	Visit 3 (Day 0) - Baseline
4	Visit 4 (Day 14)
5	Visit 5 (Day 56)
6	Visit 6 (Day 70)
7	Visit 7 (Day 238)
8	Visit 8 (Day 421)

The following labels will be used in tables, figures, and listings:

Treatment	Label
H56:IC31: 5 µg H56/500 nmol IC31	H56:IC31
Placebo	Placebo

All will be presented in UK English.

4.2 Participant Disposition

An overall summary table of the participant disposition will be prepared with number and percentages of participants in the following categories (and sub-categories):

- Screened and randomised participants
- Analysis sets (safety-, ITT-, mITT-, mITT2-, PP-, and immunogenicity analysis set)
- Cohort (safety and immunogenicity)
- End of trial status (completed, completed with recurrent TB or early termination)

- Early termination from trial including reasons, with percentage calculated using total withdrawn as denominator

The summary table will be by treatment and in total. The denominator will be the number of randomised participants and relative to randomised treatment for calculation of the percentages.

Early termination including reason will in addition be summarised by treatment and period, where period is defined as from Visit 3, Day 0 until the day before Visit 5, Day 56, from Visit 5, Day 56 until the day before Visit 7, Day 238, and from Visit 7, Day 238 until Visit 8, Day 421.

Failure to meet inclusion/exclusion criteria will be summarised by criterion overall based on all who failed to meet at least one criterion.

All disposition information will be listed. Screening failures will be listed including reason for failure. A listing of all randomised participants will be provided including randomisation number and block ID.

4.3 Baseline Characteristics and Demographics

Demographics and baseline characteristics will be presented as key characteristics:

- Age
- Age-group: 18 - 35, 36 – 60 years
- Sex
- Race
- Country

And other characteristics:

- Height
- Weight
- Body mass index (BMI)
- BMI group: 13 to <25, 25 and above kg/m^2
- Smoking status
- Site

Demographics and baseline characteristics will be listed (including details of smoking history) and summarised using descriptive statistics, by treatment and in total for the ITT analysis set. Demographics and baseline characteristics will also be summarised for the mITT analysis set in case the mITT contains less than 90% of the participants in the ITT analysis set. Similar summaries will be made for the PP analysis set in case this set contains less than 80% of the participants in the ITT analysis set.

Additional baseline characteristics deemed to be of immunologic or epidemiologic importance, have biological plausible relation to the risk of TB disease relapse or have been associated with risk of TB disease relapse in previous literature are listed below and will be grouped as indicated:

- Anemia (yes/no) defined for women as hemoglobin < 12 g/dL versus ≥ 12 g/dL, and for men as hemoglobin < 13 g/dL versus ≥ 13 g/dL
- Diabetes Mellitus versus no diabetes, (yes/no), defined as participants with medical history high level term *Diabetes mellitus (incl subtypes)* which includes non-insulin dependent types.
- Any comorbidity versus no comorbidity at baseline, (yes/no), please see section 4.4 for a definition.

The additional baseline characteristics will be summarised by treatment and listed by participant for the ITT analysis set.

4.4 Medical History

Relevant medical history and surgical history is collected. Medical and surgical history will be summarised by treatment, system organ class (SOC), and preferred term (PT), and listed using the ITT analysis set.

In addition, comorbidity terms defined as participants with a history of chronic or intermittent diseases, medical conditions or symptoms judged to influence the primary endpoint as assessed by the medical expert of the trial will be summarised by treatment, SOC, and PT using the ITT analysis set. The participants will be classified by the medical expert before unblinding of the trial and the classification will be documented in the DBL minutes.

5 Exposure and Other Dosing Information

5.1 Exposure

Number of vaccinations, timing of 2nd vaccination relative to first vaccination1st, days from 2nd vaccination to end of trial, and trial duration defined as time from 1st vaccination to end of trial in days will be summarised using descriptive statistics and presented for the safety analysis set according to vaccination actually received.

All information including reason no injection was administered or not administered per protocol, date and time of injection, injection site, whether injection site was examined and whether there were any post dose adverse events (AEs) will be listed by participant and injection number.

5.2 Concomitant medication and TB treatment history

Concomitant medication at baseline and changes in concomitant medication during the trial will be recorded. All concomitant medication including new TB treatment will be summarised by ATC level 4 term and generic drug name and treatment. Concomitant medication as well as new TB treatment will be listed using the ITT analysis set.

TB diagnosis and treatment history will be recorded at the first and second screening visit. Time from TB diagnosis to screening visit 2, TB treatment, Time from 1st vaccination to TB treatment stop date, Duration of TB treatment at screening visit 2, Time from completion of 22 weeks of TB treatment to screening visit 2, and Time from completion of 22 weeks of TB treatment to 1st vaccination will be summarised and all information (date of TB diagnosis, start and completion date of treatment for current episode) will be listed for the ITT analysis set. See section 8.2 for handling of partial or missing dates.

5.2.1 Prohibited Medication

Prohibited medication during the trial comprises receipt of:

- Investigational drug or investigational vaccine from visit 1 until and including visit 8 (Day 421)
- Licensed vaccine from visit 1 until and including visit 6 (Day 70) except for SARS-Cov-2 vaccines recommended by national vaccination programs if administered more than 28 days before or after IMP.
- Treatment likely to modify the immune response (e.g., blood products, immunoglobulins, immunosuppressive treatment) from 42 days before visit 3 until and including visit 6 (Day 70). Inhaled and topical corticosteroids are permitted.

Please see appendix D for a definition.

Prohibited medication received during the trial will be listed by participant.

6 Statistical Methodology for Efficacy Endpoints

All analyses with trial site as an effect will be performed without trial site as an effect if data is too sparse.

6.1 Time-to-event analyses

Time-to-event analyses will have start- and end-timepoint depending on the endpoint and analysis set as described in Table 1 and Table 2 below:

Table 1: Start-timepoints in time-to-event analyses

Endpoints	Population	Start-timepoint (Day=0)
All	All	Excluded from analysis if withdrawal or event before the day of the start-timepoint.
Primary endpoint (TB recurrence)	PP	Date of 2nd vaccination + 14 days
Primary endpoint (TB recurrence) Secondary endpoint (TB disease relapse) Secondary endpoint (TB disease reinfection) 1st exploratory endpoint (TB recurrence or new TB treatment) 2nd exploratory endpoint (TB recurrence - Xpert MTB/RIF Ultra or culture of sputum)	mITT	1. If received 2nd vaccination then date of 2nd vaccination + 14 except if withdrawn before 2. If missed 2nd vaccination and visit 6 is within ±3 days visit window (Day 67 to 73) then visit 6 3. Else Day 70 except if withdrawn before
	ITT	Date of 1st vaccination
3rd exploratory endpoint (TB recurrence)	mITT2	Date of 1st vaccination + 30 except if withdrawn before

If TB event is not within the period between the start-timepoint and end-timepoint, then the participant will be censored as described in Table 2. Events on the day of the start time-point are included in the analyses with a time-to-event duration of 1 day.

Table 2: End-timepoints in time-to-event analyses

Endpoint	Population	End-timepoint
All	All	Completing the trial, terminating early or lost-to-follow-up without events are censored at the day of the last visit. End-timepoint is always on the day or after the start-timepoint.
Primary endpoint (TB recurrence)	PP mITT ITT	Event: 1. Date of sputum collection for culture-confirmed TB disease Censored: Earliest date of the following: 1. Date of last visit or TC, regardless of whether two sputum samples were collected 2. Date of sputum collection resulting in positive Xpert MTB/RIF Ultra (if followed by new TB treatment) for culture negative participants 3. Date of onset of new TB treatment, in the absence of any prior culture-confirmed TB disease recurrence

TB disease relapse	mITT ITT	Event: 1. Date of sputum collection for culture-confirmed TB disease relapse Censored: Earliest date of the following: 1. Date of last visit or TC, regardless of whether two sputum samples were collected 2. Date of sputum collection resulting in confirmed TB disease reinfection 3. Date of sputum collection resulting in positive Xpert MTB/RIF Ultra (if followed by new TB treatment) for culture negative participants 4. Date of onset of new TB treatment, in the absence of any prior culture-confirmed TB recurrence
TB disease reinfection	mITT ITT	Event: 1. Date of sputum collection for culture-confirmed TB disease reinfection Censored: Earliest date of the following: 1. Date of last visit or TC, regardless of whether two sputum samples were collected at the last visit 2. Date of sputum collection resulting in confirmed TB disease relapse 3. Date of sputum collection resulting in positive Xpert MTB/RIF Ultra (if followed by new TB treatment) for culture negative participants. 4. Date of onset of new TB treatment, in the absence of any prior culture-confirmed TB recurrence
1st Exploratory TB recurrence or new TB treatment	mITT ITT	Event: Earliest date of the following: 1. Date of sputum collection for culture confirmed TB disease 2. Onset TB treatment (in the absence of any prior culture-confirmed TB disease recurrence) Censored: 1. Date of last visit or TC, regardless of whether two sputum samples were collected
2nd Exploratory TB recurrence - Xpert MTB/RIF Ultra or culture of sputum	mITT ITT	Event: Earliest date of the following: 1. Date of sputum collection for confirmed TB disease recurrence 2. Date of sputum collection for Xpert MTB/RIF Ultra-confirmed TB disease recurrence Censored: Earliest date of the following: 1. Date of last visit or TC, regardless of whether two sputum samples were collected at the last visit

		2. Date of onset of TB treatment (in the absence of any prior culture- or Xpert-confirmed TB disease recurrence)
3rd Exploratory TB recurrence	mITT2	Event: Date of sputum collection for culture-confirmed TB disease no earlier than 30 days after 1st vaccination Censored: Earliest date of the following: 1. If received 2nd vaccination then date of 2nd vaccination + 14 except if withdrawn before, else if missed 2nd vaccination and visit 6 is within ±3 days visit window (Day 67 to 73) then visit 6 else Day 70 2. Date of last visit or TC, regardless of whether two sputum samples were collected 3. Date of sputum collection resulting in positive Xpert MTB/RIF Ultra (if followed by new TB treatment) for culture negative participants 4. Date of onset of new TB treatment, in the absence of any prior culture-confirmed TB disease recurrence

Time to event (or censoring) in days will be calculated as

$$Date_{end\text{-}timepoint} - Date_{start\text{-}timepoint} + 1$$

Censoring will only be used if no events are available after the start timepoint. If last visit is used as censoring and the last visit occurs later than the visit window of visit 8 then day 428 will be used as end timepoint. Participants censored later than day 428 due to other censoring events will not be transferred to day 428.

New TB treatment is defined in Appendix E.

The trial was designed for the primary endpoint to be evaluated using a one-side α-level of 10%, therefore a one-sided log-rank p-value and 80% VE profile confidence limits will be presented for the primary endpoint. Two-sided p-values and 95% VE profile confidence intervals will be presented as well.

6.2 Analysis and Presentation of the Primary Endpoint

The primary endpoint is detection of TB disease recurrence (relapse or reinfection), defined as TB diagnosed by confirmation of *Mtb* by culture of sputum, during the period starting 14 days after the 2nd vaccination (Day 70, Visit 6) and ending 12 months after the 2nd vaccination (Day 421, Visit 8) as detailed in Table 1 and Table 2.

The primary analysis set for efficacy will be the mITT analysis set (defined in Section 3). The primary efficacy endpoint will in addition be analysed using the ITT and PP analysis sets. The analysis specified for the ITT and PP are to be regarded as supportive evidence.

For a participant to meet the primary endpoint (TB recurrence), a confirmation of *Mtb* by at least one culture positive result of the two separate sputum samples collected is required. In addition, samples sent for culture without TB symptoms and with positive results are considered as having met the primary endpoint. The number (and percentage) of participants meeting the primary endpoint will be summarised by treatment group and trial site and also by treatment group and trial period.

Time to primary endpoint (TB recurrence) will be estimated using the Kaplan-Meier (KM) method and compared between treatment groups stratified by trial site. The stratified log-rank statistic will be used to test the null hypothesis of no difference in the rates of primary endpoint (TB recurrence) over the follow-up period in the H56:IC31 compared to the placebo group. The trial was designed for the primary endpoint to be evaluated using a one-side α-level of 10%, thus the lower one-sided p-value for the log-rank test will be presented. If the p-value for the log-rank test is below 0.10 then the primary objective of the trial is considered met. The Median time to TB and the p-value for a two-sided test will be presented as well.

Time to primary endpoint (TB recurrence) will be presented by treatment in cumulative plots, i.e., inverted KM estimates. One plot per trial site will be made. Time to censoring will be marked on the curves and number of participants at risk per month from 14 days post 2nd vaccination (or Day 70 for those who did not receive a second vaccination) will be presented. Month will be calculated as days divided by 30.25 and rounded to nearest integer.

Furthermore, time to primary endpoint (TB recurrence) will be presented by treatment in cumulative plots without stratification by trial site. Two plots will be presented, one plot including 80% confidence bands and one including 95% confidence bands.

The primary endpoint will additionally be analysed using a Cox proportional hazard regression model. The Cox proportional hazard model relies on the assumption of proportional hazards over time. The proportionality of the hazards by treatment will be evaluated using a graphical comparison of log-minus-log survival curves. If the proportional hazard assumption is found to be violated, the Cox regression model will be extended appropriately, e.g., by introducing a time-dependent variable or include trial sites as strata. The Cox proportional hazard model will include treatment and site as fixed effects. Treatment group inference will be evaluated using a two-sided likelihood ratio test. Vaccine efficacy (VE) will be calculated as 1 minus the hazard ratio for H56:IC31 versus placebo and presented together with both 80% and 95% profile confidence limits.

As a sensitivity analysis, the above will be repeated:

- Excluding participants who received 2nd vaccination outside the +/- 10 days visit window i.e., before day 46 or after day 66.
- Excluding positive results of samples sent for culture without TB symptoms or positive GenExpert.

The cumulative incidence of primary endpoint (TB recurrence) per 100 person-years with associated 95% confidence intervals during follow-up will be summarised by treatment group and by treatment group and trial site. Person-days of observation will be used to estimate the time at risk of primary endpoint (TB recurrence) and will be calculated based on participant's date of last contact with the

trial or date of primary endpoint (TB recurrence) - whichever is earlier - minus the date of the 2nd vaccination plus 14 days. Person-years of observation will be calculated as person-days of observation divided by 365.25. The incidence of primary endpoint (TB recurrence) will be calculated as the number of cases of primary endpoint (TB recurrences) diagnosed during trial follow-up, divided by the total person-years of observation.

Comparison of the incidence of primary endpoint (TB recurrence) between treatment groups will be performed using relative risk summaries and corresponding 95% confidence intervals.

Supportive robustness and consistency analysis will be performed using the PP and ITT analysis sets (defined in Section 3).

All information from the two separate sputum samples collected at screening (Visit 1 and 2), Visit 8, STB Visit, and ET Visit will be listed by treatment, participant and visit for the ITT analysis set.

6.2.1 Primary efficacy endpoint evaluated in subgroups

Additional analyses of the primary efficacy endpoint will include a Cox proportional hazards regression model to examine selected variables. The analyses will be based on the mITT analysis set. The following baseline covariates will be explored to assess the impact on the vaccine efficacy:

- trial site
- country
- BMI
- age-group
- sex at baseline
- smoking status
- anemia
- diabetes mellitus
- other significant comorbidity at baseline.

See section 4.3 for definition of categories.

Furthermore, the effect of the following will be analysed:

- use of steroids and anti-inflammatory drugs during trial will be grouped into ‘use’ and ‘no use’, see Appendix C: Steroids and anti-inflammatory drugs for a definition.
- number of vaccinations

For all categorical variables, the largest subgroup will be used as reference for the model estimation.

Subgroup effect will be analysed using a Cox proportional hazards regression model including treatment, subgroup and the interaction between treatment and subgroup. Vaccine efficacy will be calculated as 1 minus the hazard ratio for H56:IC31 versus placebo and presented together with the associated 95% profile confidence limits. A p-value for the joint test of interaction between treatment and subgroup will be presented, this test should be taken with caution due to few expected events and low power. Similar models will be applied for all the categorical variables. The estimated vaccine

efficacy with 95% profile confidence limits will be presented in a forest plot overall and by the above categories.

Time to TB disease recurrence will be presented by treatment and category in cumulative plots, i.e., 1 minus the KM estimates. There will be one plot for each of the above variables.

The Covid-19 pandemic will potentially have an effect on the trial conduct and on the participants. Participants will be divided into those with a relevant Covid-19 related major protocol deviation and those without, and the impact of the Covid-19 lock-down on the efficacy endpoint will be explored using an analysis a Cox proportional hazards regression model including treatment, Covid-19 related major protocol deviation or not and the interaction between treatment and Covid-19 related protocol deviation or not.

A similar exploratory analysis will be made for participants having an adverse event with the preferred term 'Corona virus infection' or 'Coronavirus test positive'.

An analysis will be omitted if data is too sparse in any of the subgroups in question.

6.3 Analysis and Presentation of the Secondary Efficacy Endpoints

The secondary efficacy endpoints are:

- Rate of TB disease relapse
- Rate of TB disease reinfection

The relatedness of strains will be analysed by whole genome sequencing (WGS) using two different methods providing the single nucleotide polymorphism (SNP) distance (according to whole genome SNP analysis) and the Allele distance (according to core genome multi locus sequence typing (MLST) analysis) and the results will be categorised as follows:

The below thresholds will apply for the paired genetic variation between the Mtb isolates sampled at the screening visit and the recurrence visit:

- A distance of ≤ 5 SNPs or alleles will define a recent transmission chain, i.e. the same strain (likely relapse)
- A distance between > 5 and ≤ 12 SNPs or alleles will define strains that are genetically related (interpretation case by case are required)
- With a distance above 12 SNPs or alleles the two strains are not closely related (reinfection)

Inconsistency between SNP and allele distance will be evaluated case by case before DBL.

The SNP and allele distances will be summarised by recurrence and overall, including mean (SD), median, quartiles and minimum and maximum values. SNP and allele will be categorized using the above thresholds and summarised. TB strain information including WGS distance and tNGS lineage will be presented in listings.

Tb recurrence will be summarised by the subgroups mentioned in section 6.2.1 and type of recurrence (TB relapse, TB reinfection or undetermined).

6.3.1 Rate of TB disease relapse

TB disease relapse is defined as participants meeting the primary endpoint of TB disease recurrence AND determined by WGS of the *Mtb* isolate to be the same strain of *Mtb* as in the participant's original isolate from the time of diagnosis.

The analysis set for Rate of TB disease relapse will be the mITT set and the analysis will be repeated using the ITT analysis set (defined in section 3).

If TB disease relapse is not confirmed between start-timepoint and Day 421 (end-of-trial), the endpoint will be censored as described in Table 2.

Time to TB disease relapse will be estimated using the KM method and presented by treatment in a cumulative plot (inverted KM estimates) with 95% confidence bands, median time to TB, and the p-value from a two-sided log-rank test.

The endpoint will additionally be analysed using a Cox proportional hazard regression model, including treatment and site as categorical effects. Treatment group inference will be evaluated using a two-sided likelihood ratio test. Vaccine efficacy (VE) will be calculated as 1 minus the hazard ratio for H56:IC31 versus placebo and presented together with both 80% and 95% profile confidence limits.

The incidence of TB disease relapse per 100 person-years of follow-up and associated 95% confidence limits will be presented by treatment and trial site. The relative risk between H56:IC31 and placebo with 95% confidence limits will be presented as well.

6.3.2 Rate of TB disease reinfection

TB disease reinfection is defined as participants meeting the primary endpoint of TB disease recurrence AND determined by WGS of the *Mtb* isolate to be a different strain than in the participant's original isolate from the time of diagnosis.

The analysis set for Rate of TB disease reinfection will be the mITT set, and the analyses will be repeated for the ITT analysis set (defined in section 3).

If TB disease reinfection is not confirmed within the start-timepoint and Day 421 (end-of-trial), the endpoint will be censored as described in Table 2.

The number (and percentage) of participants meeting this secondary endpoint will be summarised by treatment group.

Time to TB disease reinfection will be estimated using the KM method and presented by treatment in a cumulative plot (inverted KM estimates) with 95% confidence bands, median time to TB, and the p-value from a two-sided log-rank test.

The endpoints will additionally be analysed using a Cox proportional hazard regression model, including treatment and site as categorical effects. Treatment group inference will be evaluated using

a two-sided likelihood ratio test. Vaccine efficacy (VE) will be calculated as 1 minus the hazard ratio for H56:IC31 versus placebo and presented together with both 80% and 95% profile confidence limits.

The incidence of TB disease reinfection per 100 person-years of follow-up and associated 95% confidence limits will be presented by treatment. The relative risk between H56:IC31 and placebo with 95% confidence limits will be presented as well.

6.4 Analysis and presentation of the secondary immunogenicity endpoints

The secondary immunogenicity endpoints are:

- Antigen specific cell mediated immune responses by WB ICS
- Humoral immune responses by IgG ELISA

The immunogenicity analysis set will be used for these endpoints, and the immunogenicity cohort will be used for an exploratory analysis.

6.4.1 Antigen specific cell mediated immune responses by WB ICS

Antigen specific cell mediated immune responses by WB ICS at baseline (Visit 3, Day 0), and 14 days after the 2nd vaccination (Visit 6, Day 70) is a secondary endpoint and the primary immunogenicity endpoint. For assessment of the immunogenicity of H56:IC31 by WB ICS, only whole blood samples from the immunogenicity cohort are included (See sections 1 and 2.2).

Responses will be measured by flow cytometry (up to 15 parameters) with the WB ICS assay. The variables of interest for assessment of antigen-specific cell-mediated immune response to vaccination will be the percentage of $CD4^+$ and $CD8^+$ T-cells that express the cytokines IL-2, IFN-γ, TNF-α, and IL-17 in the following combinations:

- H56 protein-specific $CD4^+$ T-cells expressing the total cytokine response, i.e., any combination of IL-2, IFN- γ, TNF-α, and/or IL-17
- H56 protein-specific $CD4^+$ T-cells co-expressing IL-2 and TNF-α
- H56 protein-specific $CD4^+$ T-cells co-expressing IL-2, IFN- γ, and TNF-α
- H56 protein-specific $CD8^+$ T-cells expressing any combination of IL-2, IFN-g, TNF-α, and/or IL-17 (total response)

The percentages of T-cell responses will be presented in summary tables and box plots including median, quartiles and range by treatment and visit including change from Visit 3 to Visit 6.

The immunogenicity analysis set will also be used for analysis of antigen specific cell mediated immune responses by WB ICS, please see Appendix A.

6.4.2 Humoral immune responses by IgG ELISA

Antigen-specific antibody will be assessed in plasma by IgG ELISA. This endpoint will be measured at baseline (Visit 3, Day 0) and 14 days after the 2nd vaccination (Visit 6, Day 70).

For assessment of the immunogenicity of H56:IC31, by IgG ELISA, only plasma samples measured at Visit 3 (Day 0) and Visit 6 (Day 70) for participants in the immunogenicity cohort are included (See

sections 1 and 2.2). All other IgG ELISA plasma samples taken from participants in the trial are defined as exploratory immunology/immunological correlate samples and are not the scope of this SAP.

Summaries will include immune response at visit 3 (Day 0) and visit 6 (Day 70) as well as fold increase from Day 0 to Day 70. Antibody titer will be presented in a plot by treatment and time. The immunogenicity analysis set will be used for analysis of humoral immune responses by IgG ELISA.

All visit 3 and visit 6 anti-H56 IgG antibody measurements for all participants in the immunogenicity cohort will be listed.

6.5 Analysis and presentation of exploratory efficacy endpoints

Three exploratory efficacy endpoints linked to the primary endpoint are defined as follows:

1. Rate of TB recurrence, defined as participants meeting the primary endpoint of TB recurrence or who started TB treatment without confirmation of *Mtb* by culture of sputum
2. Rate of TB recurrence, defined as participants meeting the primary endpoint of TB disease recurrence based on confirmation of *Mtb* by Xpert MTB/RIF Ultra or culture of sputum
3. Rate of TB recurrence, defined as participants meeting the primary endpoint of TB disease recurrence or diagnosed between 30 days after the 1st vaccination and 14 days after the 2nd vaccination, based on confirmation of *Mtb* by culture of sputum

The analysis set for the 1st and 2nd exploratory endpoint (1. and 2. above) will be the mITT set and these analyses will be repeated using the ITT analysis set. The 3rd exploratory endpoint (3. above) will be analysed using the mITT2 set. See section 3 for definition of analysis sets.

The following analyses will be performed for the three exploratory endpoints: Time to TB disease recurrence will be estimated using the KM method and presented by treatment in a cumulative plot (inverted KM estimates) with 95% confidence bands, median time to TB, and the p-value from a two-sided log-rank test.

The endpoints will additionally be analysed using a Cox proportional hazard regression model, including treatment and site as categorical effects. Treatment group inference will be evaluated using a two-sided likelihood ratio test. Vaccine efficacy (VE) will be calculated as 1 minus the hazard ratio for H56:IC31 versus placebo and presented together with both 80% and 95% profile confidence limits.

The incidence of TB disease recurrence per 100 person-years of follow-up and associated 95% confidence limits will be presented by treatment. The relative risk between H56:IC31 and placebo with 95% confidence limits will be presented as well.

The Cox proportional hazard analysis will be repeated including country instead of site as categorical effect.

Details will be listed by trial site and participant.

6.5.1 1st exploratory endpoint: Rate of TB disease recurrence (relapse or reinfection)

1st exploratory Endpoint, Rate of TB disease recurrence (relapse or reinfection), is defined as participants meeting the primary endpoint of TB disease recurrence or who started TB treatment without confirmation of *Mtb* by culture of sputum.

The number (and percentage) of participants meeting the 1st exploratory endpoint will be summarised by treatment group. The summary will include the number of participants who started new TB treatment without culture confirmation of TB recurrence.

6.5.2 2nd exploratory endpoint: Rate of TB disease recurrence (relapse or reinfection)

2nd exploratory endpoint, Rate of TB disease recurrence (relapse or reinfection), is defined as participants meeting the primary endpoint of TB disease recurrence based on confirmation of *Mtb* by Xpert *MTB*/RIF Ultra or culture of sputum.

The number (and percentage) of participants meeting the 2nd exploratory endpoint will be summarised by treatment group. The summary will include the number of participants positive by Xpert *MTB*/RIF Ultra only and by Xpert *MTB*/RIF Ultra and culture.

6.5.3 3rd exploratory endpoint: Rate of TB disease recurrence (relapse or reinfection)

3rd exploratory endpoint, Rate of TB disease recurrence (relapse or reinfection), is defined as participants meeting the primary endpoint of TB disease recurrence AND participants diagnosed between 30 days after the 1st vaccination and 14 days after the 2nd vaccination, based on confirmation of *Mtb* by culture of sputum. The endpoint is similar to the primary endpoint, except that TB disease recurrence diagnosed between 30 days after the 1st dose and 14 days after the 2nd dose (or Day 70) is included as well.

The analysis set for this endpoint will be the mITT2 set.

The number (and percentage) of participants meeting the 3rd exploratory endpoint will be summarised by treatment group.

6.6 Multiplicity adjustments

In this two-armed trial there is no multiplicity issue with more comparators.

The primary analysis of the primary endpoint is based on the mITT analysis set. Analysis of the primary endpoint using other analysis sets are considered sensitivity analysis and adjustment for multiplicity is not necessary. The exploratory endpoints are exploratory in nature and no adjustment for multiplicity will be done.

The secondary endpoints, rate of TB disease relapse and reinfection are subdivisions of the primary endpoint, and no adjustment for multiplicity will be done.

For other secondary endpoints, no formal statistical analysis will be performed.

6.7 Sub-group and Centre Effects

The primary endpoint will in addition to the primary analysis be analysed using a Cox proportional hazard model including different categorical variables deemed to be of immunologic or epidemiologic importance, have biological plausible relation to the risk of TB disease relapse or have been associated with risk of TB disease relapse in previous literature. Please see section 6.2.1. for details.

The trial is multi-centre trial, and adjustment for centre effects for the statistical analyses is planned.

7 Statistical Methodology for Safety Endpoints

Safety will be considered for participants included in the Safety Analysis Set and reported by actual received treatment. No imputation of missing data is planned for safety endpoints except for imputation of partial dates, see section 8.2.

7.1 Safety Endpoints

The secondary safety endpoints are the following:

- Solicited adverse events occurring the first 7 days after each vaccination and all adverse events occurring the first 14 days after each vaccination
- Serious adverse events including medically important events occurring from the 1st vaccination through the end of the trial

Additional safety assessments are:

- Adverse events of special interest (AESIs) in the entire post-vaccination trial period
- Vital signs
- Weight
- Symptom directed physical examination
- Safety laboratory parameters

7.2 Analysis and Presentation of Safety Endpoints

7.2.1 Adverse Events

AEs will be regarded as treatment emergent AEs (TEAEs) if they occur after the 1st vaccination.

The collection periods for AEs are shown in the below table:

Table 3: Collection of AEs

Type of Event	Collection Period
Unsolicited adverse events (non-serious)	First 14 days after each vaccination (spontaneous adverse events, if any) Diary review and interview at study visit 14 days after each vaccination.
Solicited adverse events	First 7 days after each vaccination (solicited adverse events recorded daily in diary card) Diary review and interview at study visit 14 days after each vaccination.
Adverse events of special interest	Entire post-vaccination study period (i.e., 421 days).
Serious adverse events including medically important adverse events	Entire post-vaccination study period (i.e.,421 days).

Solicited adverse events are defined as events occurring within 7 days after a vaccination and of the following types:

- the injection site reactions *redness, swelling*, and *tenderness/pain*
- the systemic adverse events f*ever* (i.e., events with PT *pyrexia* also named temperature reactions)*, arthralgia, myalgia, fatigue, headache, rash, chills,* and *nausea*.

Solicited injection site reactions will be considered related to the IMP regardless of the causality assessment by the investigator. Therefore, related events consist of both solicited events and investigator-defined related events. Related AEs are defined as adverse reactions (ARs).

Presentations of serious adverse events (SAEs) will include medically important AEs.

An overall summary table of treatment emergent AEs by treatment will be made. The overall summary table will include number of events, number of participants, and proportion of participants in the safety analysis set reporting TEAEs (including solicited AEs), solicited AEs, AESIs, Treatment emergent SAEs, Fatal SAEs, related AEs, related SAEs, suspected unexpected SARs (SUSAR), AEs leading to discontinuation of IMP, AEs leading to discontinuation of trial, TEAEs by severity, and TEAEs by outcome. The same will be repeated for AEs occurring within 14 days after vaccination, SAEs, AESIs, solicited AEs and solicited SAEs occurring within the 7 days after each vaccination, and unsolicited AEs and SAEs occurring within the first 14 days after each vaccination.

Treatment emergent AEs, AEs within 14 days after vaccination, solicited AEs and solicited SAEs occurring within the 7 days after each vaccination, and unsolicited AEs and SAEs occurring within the first 14 days after each vaccination will be summarised by SOC and PT. The summaries will include number of events, number of participants, and proportion of participants reporting these events and will be tabulated by treatment. Additional summaries by SOC and PT will present number of events, and number and proportion of participants with AEs within 14 days after vaccination by severity, by causality, by age group (18-35 years, 36 years ->), and by sex.

The number of participants with solicited injection site reactions will be presented in a plot by type of reaction and maximum severity. The number of participants with solicited systemic events will also be presented in a plot by PT and maximum severity.

AESIs will be defined as either an AE marked by the investigator as an AESI or if the AE is covered by the list of PTs specified in the protocol, see Appendix B. AESIs are meant to be collected throughout the post-vaccination trial period. AESIs will be summarised by SOC and PT, including number of events, number of participants, and proportion of participants reporting these events by treatment arm. Similar summaries will be made for SAEs including medically important events.

The following listings of AEs will be made:

- AEs
- Solicited injection site reactions within the first 7 days after each vaccination
- Solicited systemic reactions within the first 7 days after each vaccination
- Unsolicited AEs within the first 14 days after each vaccination
- ARs (including SARs and SUSARs)
- AESIs
- SAEs
- AEs leading to withdrawal from treatment or trial

- Fatal SAEs
- Injection site reactions and systemic events occurring more than 14 days after vaccination
- Other non-serious adverse events occurring more than 14 days after vaccination, i.e., events not included in any of the above listings

AEs occurring before first vaccination including AEs in screening failures and in randomised participants never exposed to trial drug will be presented in a separate listing, if applicable.

7.2.2 Other Safety Assessments

Injection site reactions

Injection site reactions (*redness*, *swelling*, *tenderness/pain*, and *other* as judged by the investigator) and axillary lymphadenopathy, defined as Lowest Level Term Lymphadenopathy axillary, on the same day as a vaccination as well as all injection site reactions after latest vaccination will be presented as follows:

- The number and percentage of participants as well as number of events will be summarised by treatment group and by vaccination (starting after 1st and after 2nd vaccination).
- The maximum size of the redness and swelling on the same day as a vaccination and in total within 7 days after latest vaccination will be summarised by treatment group and by vaccination.
- Injection site reactions will be listed including type and maximum diameter in mm and onset relative to the two vaccinations.

Temperature reactions (pyrexia)

Temperature reactions are events with PT *Pyrexia.* The maximum temperature could be recorded in the CRF. The maximum temperatures will be summarised by treatment group and vaccination (1st and 2nd). A listing will be made for all systemic reactions including pyrexia with maximum temperature if available.

Vital Signs

Vital signs (systolic and diastolic blood pressure, pulse, and axillary temperature) will be measured at each visit from 2nd screening visit (Visit 2) to Visit 6 (Day 70), and at ET visit. At Visits 3 and 5, the measurements are taken both pre-vaccination and one-hour post-vaccination.

Vital signs will be summarised by visit, including change from pre-vaccination to post-vaccination within Visit 3 and 5, respectively. For each visit it will be flagged whether there are any abnormal clinically significant vital signs. All information will be listed.

Height, Weight, and BMI

Weight is measured at all onsite visits from 1st screening visit (Visit 1) and onwards. Weight will be summarised by treatment and visit, including change from baseline, (Visit 3, Day 0) to subsequent visits. Height is measured at 1st screening visit (Visit 1) and BMI will be calculated for that visit. Height and BMI will be summarised by treatment, see section 4.3. All information will be listed. Furthermore, a box plot will present weight by visit and treatment.

Physical Examination

A complete physical examination is performed at 2nd screening visit (Visit 2). Symptom directed physical examination is performed at the two vaccination visits, Visit 3 and Visit 5. Each body system

of the physical examination will be evaluated as normal or abnormal, and if abnormal clinically significant or not. Abnormal clinically significant findings will be listed by participants.

TB symptoms
From visit 4 (Day 14) and throughout the trial TB symptom screen will be performed. TB signs or symptoms will be summarised by symptom, treatment, and visit, including telephone contact (TC) visits. All signs or symptoms that occur will be listed. If a symptom screen was not performed, this will be in the listing including the reason why symptom screen was not performed.

Pregnancy test
Pregnancies and pregnancy outcomes will be listed.

7.2.3 Laboratory Safety Data

Laboratory safety (haematology, biochemistry, and urine analysis parameters) are measured at 2nd screening visit (Visit 2) for all participants, and at Visit 4 (day 14), Visit 6 (day 70) and at ET visit for participants in the safety cohort. Laboratory safety will also be measured at the ET visit if the visit occurs within 14 days after investigational product administration. Additional laboratory tests may be performed if deemed necessary by the investigator for evaluation of an AE.

The following safety laboratory parameters are measured and will be presented using SI units:

- Serum chemistry: AST (μKat/L), ALT (μKat/L), ALP (μKat/L), GGT (μKat/L), total bilirubin (μmol/L), creatinine (μmol/L).
- Hematology: haemoglobin (g/L), haematocrit (L/L), leukocytes (10^9/L), lymphocytes (10^9/L), monocytes (10^9/L), neutrophils (10^9/L), basophils (10^9/L), eosinophils (10^9/L), and platelets (10^9/L).
- Urine analysis: urine protein, glucose, leukocytes, and erythrocytes (microscopy if positive by dipstick).

Laboratory safety biochemistry and haematology will be presented by visit and treatment using summary tables and boxplots. Urinalysis will be summarised by visit and treatment using the categories as collected in the eCRF.

All safety laboratory data will be listed by participant, including unscheduled measurements. Values outside normal ranges will be flagged and presented in a separate listing including normal ranges.

7.3 Interim Analysis

To identify any possible safety issues, two blinded reviews of reported SAEs, AEs including AEs of special interest, injection site reactions and laboratory safety data were performed after:

- The first 150 participants across all sites had received their 1st vaccination and the 14 days safety follow-up data were available
- The first 150 participants across all sites had received their 2nd vaccination and the 14 days safety follow-up data were available

No comparison of treatment arms was done during the blinded safety reviews and therefore an adjustment of the α-level is not relevant.

In protocol amendment 3, a partial unblinding using dummy IDs was introduced to allow analysis of WB ICS data. The trial team will remain blinded. Please see the protocol section 7.6.2. for details. As for the other exploratory endpoints, no adjustment for multiplicity will be made.

8 Data handling and programming rules

8.1 Handling of Missing Values

For the primary efficacy endpoint missing values will be handled using censoring. The primary endpoint is analysed based on the mITT which includes all randomised participants except those with TB disease recurrence before Visit 6, Day 70 (or 14 days after 2nd dose for those who received both vaccinations). Participants without TB disease recurrence confirmed by of *Mtb* by culture of sputum samples are censored. Asymptomatic participants not capable of producing sputum will be censored as well.

No imputation of missing values will be performed.

8.2 Partial and missing dates

Partial TB diagnosis and TB treatment start dates will be handled as follows: If day is missing, the day will be set to the 1st of the month. If the month is missing the month will be set to January. If the year is missing the date will be set to missing.

Partial TB treatment end dates will be handled as follows: If day is missing, day will be set to the last day of the month. If the month is missing, the month will be set to six months after the start month.

Partial dates of general concomitant medication and medical history will not be imputed.

Partial AE start dates will be handled as follows: If day is missing then day will be set to the first day of the month unless a vaccination occur in the same month. In that case day will be set to the day of vaccination. If month is missing the month will be set to the first month of the year unless at least one vaccination occurs that year. In that case the month will be set to the month of the first vaccination of the year. If the AE start date is missing the date will be set to the date of the first vaccination.

Partial AE end dates will be handled as follows: If the day is missing, the day will be set to the last day of the month. If month is missing, month will be set to the last month of the year. If the AE end date is missing the AE will be considered ongoing at end of trial and the date will not be imputed.

8.3 Other derivations

Duration of AEs

Duration of an AE in days will be calculated as:

$$Date_{AE\ end} - Date_{AE\ start} + 1$$

The calculation will be based on AE dates after handling of partial dates. Duration will not be calculated for ongoing AEs.

Time to event

Time to event (or censoring) in days will be calculated as

$$Date_{end\text{-}timepoint} - Date_{start\text{-}timepoint} + 1$$

9 Deviations from protocol

The following deviations in the statistical analyses compared to the protocol are made:

- The protocol section 6.1 states that the per-protocol [PP] analysis set will consist of all participants who received both doses of H56:IC31 or placebo within the specified dose intervals, who entered the evaluation period for efficacy 14 days after receipt of the second dose of H56:IC31 or placebo with no HIV seroconversion, and who had no major protocol deviations (to be defined in the statistical analysis plan). Regarding major protocol deviations, the definition is updated to *who had no major protocol deviation of clinical or statistical significance*.
- The protocol section 7.3.1 states that supportive robustness and consistency analysis will be performed using the PP and ITT populations for the primary endpoint. Since
    - the only difference between the mITT and the ITT population is that the mITT will include all randomised participants except those with TB disease recurrence before Visit 6, Day 70
    - the primary endpoint only include TBs diagnosed by confirmation of *Mtb* by culture of sputum, during the period starting 14 days after the 2nd vaccination (Day 70, Visit 6)

  then are the mITT and ITT analyses exactly identical, why the ITT analyses of the primary endpoint from day 70 will be replaced by analyses from day 0.
- The protocol section 7.3.1 states that summaries of median time to initial diagnosis of TB disease recurrence will be presented by treatment group and trial site. Due to the expected low number of recurrent TB diseases, it will not be possible to estimate the median time to initial diagnosis and this is therefore not included in the SAP. The endpoint contains censored events and a non-parametric summary of time to TB disease recurrence is not appropriate.

10 Software

All statistical calculations described in this SAP will be done by [redacted] using SAS, release 9.4 or later (SAS Institute, Cary, NC, USA).

Who drug dictionary version September 2018 will be used for coding of prior and concomitant medication.

MedDRA version 21.1 will be used for coding of medical history and AEs.

Appendix A: Immunogenicity SAP

Appendix A contains the final immunogenicity SAP by [redacted] and [redacted] dated 04 September 2023.

H56:IC31 vaccine immunogenicity statistical analysis plan

1. Background: This statistic analytical plan (SAP) will outline the approaches to be undertaken to analyse data for the immunogenicity endpoint in the H56:IC31 A055 trial. The key objective is to quantify and characterize immunological responses to H56:IC31 vaccination in TB patients who have completed antibiotic therapy.
The first 100 participants from [redacted] and [redacted] will be included in the immunogenicity cohort. The first 50 participants randomized at the [redacted] clinical site and the first 50 randomized at the [redacted] site will be included such that approximately half of the participants from each site would have received the vaccine and another half the placebo. Immunogenicity samples will be collected at baseline (Day 0) and 14 days after the second vaccination (Day 70), and then processed to measure antigen-specific immune responses.

Table 1: Summary of immunogenicity evaluation

Sample type	Assay	Immunogenicity endpoint	Approximate blood volume	Study days	Study site
Whole blood	WB ICS	Secondary endpoint (Primary immunogenicity endpoint)	6 ml	0, 70	[redacted]

2. Objectives:

2.1. Primary objective:
2.1.1. To determine if H56:IC31 vaccination boosts antigen-specific Th1 and Th17 T cell responses.
2.1.1.1. We will measure frequencies (background subtracted) of recombinant H56 protein-specific CD4 T-cells expressing any combination of IL-2, IFN-γ, TNF, and/or IL-17 (i.e. the total cytokine response) at Day 0 and Day 70 in each study arm.
Statistical method(s):

1. Wilcoxon signed-rank test will be used to compare responses between Day 0 and Day 70 within each study arm. A p-value < 0.05 will be considered significant.
2. Mann-Whitney test will be used to compare the baseline-corrected response (Day 70 responses minus the Day 0 responses) between the two study arms. The effect size and 95% CI will be reported and a p-value < 0.05 will be considered significant.

Mann-Whitney test will be used to compare responses across study arms at Day 70. The effect size and 95% CI will be reported and a p-value < 0.05 will be considered significant.

2.2. Secondary objective(s):
2.2.1. To determine which cytokine co-expressing T cell subsets are boosted by H56:IC31 vaccination.
2.2.1.1. We will quantify frequencies (background subtracted) of recombinant H56 protein-specific CD4 T-cell subsets that co-express combinations of IL-2, IFN-γ, TNF, and/or IL-17 at

Day 0 and Day 70 in each study arm, and determine which of these subsets predominate the vaccine-boosted response. We will focus on the following 3 T cell subsets as primary outcomes based on prior experience with H56:IC31 vaccination in human trials:

1. CD4 T-cells co-expressing IL-2 and TNF
2. CD4 T-cells co-expressing IL-2, IFN-γ, and TNF
3. CD8 T-cells expressing any combination of IL-2, IFN-γ, TNF, and/or IL-17 (total response)

We will therefore address the following objectives:

2.2.1.2. Compare frequencies (background subtracted) of recombinant H56 protein-specific CD4 T-cells co-expressing IL-2 and TNF (double positives) between Day 0 and Day 70 in each study arm, and at Day 70 across study arms.

2.2.1.3. Compare frequencies (background subtracted) of recombinant H56 protein-specific CD4 T-cells co-expressing IL-2, IFN-γ, and TNF (triple positives) between Day 0 and Day 70 in each study arm, and at Day 70 across study arms.

2.2.1.4. Compare frequencies of recombinant H56 protein-specific CD8 T-cells expressing any combination of IL-2, IFN-γ, TNF, and/or IL-17 between Day 0 and Day 70 in each study arm, and at Day 70 across study arms.

Statistical method(s):

1. Wilcoxon signed-rank test will be used to compare responses between Day 0 and Day 70 within each study arm.
2. Mann-Whitney test will be used to compare the baseline-corrected response (Day 70 responses minus the Day 0 responses) between the two study arms. The effect size and 95% CI will be reported and a p-value < 0.05 will be considered significant.
3. Mann-Whitney test will be used to compare responses across study arms at Day 70. The effect size and 95% CI will be reported and a p-value < 0.05 will be considered significant.

Appendix B: AESI

AESI as specified in the protocol, Appendix A:

Adverse events of special interest represent a subset of AEs that include autoimmune diseases and other systemic disorders of interest which could potentially have an autoimmune etiology. Adverse events of special interest are listed below. The PI should use clinical and scientific judgment in deciding whether other adverse events (i.e., events not listed here) could have an autoimmune origin.

Acute disseminated encephalomyelitis (ADEM)
Addison's Disease
Anti-neutrophil Cytoplasmic Antibody (ANCA)-associated Vasculitis
Ankylosing Spondylitis
Anti-phospholipid Syndrome
Autoimmune Bullous Skin Diseases
Autoimmune Hemolytic Anemia
Autoimmune Hepatitis
Basedow’s Disease
Behcet’s Syndrome
Bell's Palsy
Carditis
Celiac Disease
Crohn’s Disease
Cutaneous Lupus
Demyelinating Disease
Dermatomyositis
Diabetes Mellitus, Insulin Dependent (IDDM)
Erythema Nodosum
Glomerulonephritis
Guillain Barre Syndrome
Grave’s Disease
Idiopathic Thrombocytopenic Purpura (ITP)
Inflammatory Bowel Disease (non-specific)
Juvenile Rheumatoid Arthritis
Mixed Connective Tissue Disease
Multiple Sclerosis
Myasthenia Gravis
Myelitis/Transverse Myelitis
Myocarditis
Nephritis
Optic neuritis
Pericarditis

Appendix C: Steroids and anti-inflammatory drugs

Steroids and anti-inflammatory drugs of interest are defined as the below ATC level 4 codes.

ATC Code	ATC text
A07EC	AMINOSALICYLIC ACID AND SIMILAR AGENTS
C05AA	CORTICOSTEROIDS
H02AA	MINERALOCORTICOIDS
H02AB	GLUCOCORTICOIDS
H02BX	CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS
J04AA	AMINOSALICYLIC ACID AND DERIVATIVES
L04AA	SELECTIVE IMMUNOSUPPRESSANTS
L04AB	TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS
L04AC	INTERLEUKIN INHIBITORS
L04AD	CALCINEURIN INHIBITORS
L04AX	OTHER IMMUNOSUPPRESSANTS
M01AA	BUTYLPYRAZOLIDINES
M01AB	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES
M01AC	OXICAMS
M01AE	PROPIONIC ACID DERIVATIVES
M01AG	FENAMATES
M01AH	COXIBS
M01AX	OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS
M01BA	ANTIINFLAMMATORY/ANTIRHEUMATIC AGENTS IN COMBINATION WITH CORTICOSTEROIDS
M01BX	OTHER ANTIINFLAMMATORY/ANTIRHEUMATIC AGENTS IN COMBINATION WITH OTHER DRUGS
M01CA	QUINOLINES
M01CB	GOLD PREPARATIONS
M01CC	PENICILLAMINE AND SIMILAR AGENTS
M01CX	OTHER SPECIFIC ANTIRHEUMATIC AGENTS
N02BA	SALICYLIC ACID AND DERIVATIVES
N02CB	CORTICOSTEROID DERIVATIVES
V10AX	OTHER ANTIINFLAMMATORY THERAPEUTIC RADIOPHARMACEUTICALS

Appendix D: Prohibited medication

Prohibited medication is defined as the below ATC codes:

Category	ATC code	ATC Text
Immune response affecting treatments. Prohibited from 42 days before visit 3 until and including visit 6 (Day 70).	A14AA	ANDROSTAN DERIVATIVES
	A14AB	ESTREN DERIVATIVES
	B02BB	FIBRINOGEN
	B02BC	LOCAL HEMOSTATICS
	B02BD	BLOOD COAGULATION FACTORS
	B02BW	HERBAL CONTAINING VITAMIN-K
	B02BX	OTHER SYSTEMIC HEMOSTATICS
	B05AA	BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS
	B05AX	OTHER BLOOD PRODUCTS
	B06AA	ENZYMES
	B06AB	OTHER HEM PRODUCTS
	B06AC	DRUGS USED IN HEREDITARY ANGIOEDEMA
	B06AW	HERBAL DECOAGULANT
	C05AA	CORTICOSTEROIDS
	H01AA	ACTH
	H01AB	THYROTROPIN
	H01AC	SOMATROPIN AND SOMATROPIN AGONISTS
	H01AX	OTHER ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES
	H01BA	VASOPRESSIN AND ANALOGUES
	H01BB	OXYTOCIN AND ANALOGUES
	H01CA	GONADOTROPIN-RELEASING HORMONES
	H01CB	SOMATOSTATIN AND ANALOGUES
	H01CC	ANTI-GONADOTROPIN-RELEASING HORMONES
	H02AA	MINERALOCORTICOIDS
	H02AB	GLUCOCORTICOIDS
	H02BX	CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS
	H02CA	ANTICORTICOSTEROIDS
	J06AA	IMMUNE SERA
	J06BA	IMMUNOGLOBULINS, NORMAL HUMAN
	J06BB	SPECIFIC IMMUNOGLOBULINS
	J06BC	OTHER IMMUNOGLOBULINS
	L03AA	COLONY STIMULATING FACTORS
	L03AB	INTERFERONS
	L03AC	INTERLEUKINS
	L03AW	HERBAL IMMUNOMODULATORS
	L03AX	OTHER IMMUNOSTIMULANTS
	L04AA	SELECTIVE IMMUNOSUPPRESSANTS

	L04AB	TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS
	L04AC	INTERLEUKIN INHIBITORS
	L04AD	CALCINEURIN INHIBITORS
	L04AX	OTHER IMMUNOSUPPRESSANTS
	M01BA	ANTIINFLAMMATORY/ANTIRHEUMATIC AGENTS IN COMBINATION WITH CORTICOSTEROIDS
	N02CB	CORTICOSTEROID DERIVATIVES
	V07AC	BLOOD TRANSFUSION, AUXILIARY PRODUCTS
Licensed vaccines. Prohibited from visit 1 until and including visit 6 (Day 70) except for SARS-Cov-2 vaccines recommended by national vaccination programs if administered more than 28 days before or after IMP	J07AC	ANTHRAX VACCINES
	J07AD	BRUCELLOSIS VACCINES
	J07AE	CHOLERA VACCINES
	J07AF	DIPHTHERIA VACCINES
	J07AG	HEMOPHILUS INFLUENZAE B VACCINES
	J07AH	MENINGOCOCCAL VACCINES
	J07AJ	PERTUSSIS VACCINES
	J07AK	PLAGUE VACCINES
	J07AL	PNEUMOCOCCAL VACCINES
	J07AM	TETANUS VACCINES
	J07AN	TUBERCULOSIS VACCINES
	J07AP	TYPHOID VACCINES
	J07AR	TYPHUS (EXANTHEMATICUS) VACCINES
	J07AX	OTHER BACTERIAL VACCINES
	J07BA	ENCEPHALITIS VACCINES
	J07BB	INFLUENZA VACCINES
	J07BC	HEPATITIS VACCINES
	J07BD	MEASLES VACCINES
	J07BE	MUMPS VACCINES
	J07BF	POLIOMYELITIS VACCINES
	J07BG	RABIES VACCINES
	J07BH	ROTA VIRUS DIARRHEA VACCINES
	J07BJ	RUBELLA VACCINES
	J07BK	VARICELLA ZOSTER VACCINES
	J07BL	YELLOW FEVER VACCINES
	J07BM	PAPILLOMAVIRUS VACCINES
	J07BX	OTHER VIRAL VACCINES
	J07CA	BACTERIAL AND VIRAL VACCINES, COMBINED
Investigational treatment. Prohibited from visit 1 until and including visit 8 (Day 421)	V98	INVESTIGATIONAL DRUG

Appendix E: New TB treatment

New TB treatment is defined as the below ATC codes.

ATC code	ATC level	ATC Text
J04A	3	DRUGS FOR TREATMENT OF TUBERCULOSIS
J04AA	4	AMINOSALICYLIC ACID AND DERIVATIVES
J04AB	4	ANTIBIOTICS
J04AC	4	HYDRAZIDES
J04AD	4	THIOCARBAMIDE DERIVATIVES
J04AK	4	OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS
J04AM	4	COMBINATIONS OF DRUGS FOR TREATMENT OF TUBERCULOSIS
J04AW	4	HERBAL DRUGS FOR TREATMENT OF TUBERCULOSIS

Table shells

Table of Contents

Table 14.1.1.1: Disposition of participants

	H56:IC31 N (%)	Placebo N (%)	Total N (%)
Screened participants (N)			xxx
Not assigned (N)			xx
All randomised	xxx (100.0)	xxx (100.0)	xxx (100.0)
ITT analysis set	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Safety analysis set	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Modified intention-to-treat (mITT)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Second mITT (mITT2)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Per protocol (PP)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Immunogenicity analysis set	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Safety cohort	xx (x.x)	xx (x.x)	xx (xx.x)
Immunogenicity cohort	xx (x.x)	xx (x.x)	xx (xx.x)
End of Trial			
Completed	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
With recurrent TB	x (x.x)	x (x.x)	x (x.x)
Early termination	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xxx (100.0)	xxx (100.0)	xxx (100.0)
Reason for early termination			
Recurrent TB	x (x.x)	x (x.x)	x (x.x)
Adverse event	x (x.x)	x (x.x)	x (x.x)
Death	x (x.x)	x (x.x)	x (x.x)
Lost to follow-up	x (x.x)	x (x.x)	x (x.x)
Protocol deviation	x (x.x)	x (x.x)	x (x.x)
Withdrawal by participant	x (x.x)	x (x.x)	x (x.x)
Investigator decision	x (x.x)	x (x.x)	x (x.x)
Sponsor request	x (x.x)	x (x.x)	x (x.x)
Other	x (x.x)	x (x.x)	x (x.x)
Total	xxx (100.0)	xxx (100.0)	xxx (100.0)

Page 1 of x

N: Number of participants, %: Percentage of participants.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.1.2: Early termination by visit – All randomised participants

	H56:IC31 N (%)	Placebo N (%)
All randomised participants	xxx	xxx
Reason for early termination		
From Visit 3 (Day 0) to Visit 5 (Day 56)		
Recurrent TB	x (x.x)	x (x.x)
Adverse event	x (x.x)	x (x.x)
Death	x (x.x)	x (x.x)
Lost to follow-up	x (x.x)	x (x.x)
Protocol deviation	x (x.x)	x (x.x)
Withdrawal by participant	x (x.x)	x (x.x)
Investigator decision	x (x.x)	x (x.x)
Sponsor request	x (x.x)	x (x.x)
Other	x (x.x)	x (x.x)
Total	xx (xx.x)	xx (xx.x)
From Visit 5 (Day 56) to Visit 7 (Day 238)		
Recurrent TB	x (x.x)	x (x.x)
Adverse event	x (x.x)	x (x.x)
Death	x (x.x)	x (x.x)
…	…	
Total	xx (xx.x)	xx (xx.x)
From Visit 7 (Day 238) to Visit 8 (Day 421)		
Recurrent TB	x (x.x)	x (x.x)
Adverse event	x (x.x)	x (x.x)
Death	x (x.x)	x (x.x)
…	…	
Total	xx (xx.x)	xx (xx.x)

N: Number of participants, %: Percentage of participants.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.1.3: Violation of inclusion- or exclusion criteria – All screened participants	
	Total N (%)
Not eligible subjects	xxx
Inclusion criteria not met	xx (xx.x)
<criterion 1>	xx (xx.x)
<criterion 2>	xx (xx.x)
…	xx (xx.x)
Exclusion criteria met	xx (xx.x)
<criterion 1>	xx (xx.x)
<criterion 2>	xx (xx.x)
…	xx (xx.x)

Page 1 of x

N: Number of participants, %: Percentage of participants. Percentages are calculated based on the number of participants who are not eligible. Each participant may violate more than one criterion.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.1.4: Exclusion from PP analysis set – All randomised participants			
	H56:IC31 N (%)	**Placebo N (%)**	**Total N (%)**
All randomized	xxx	xxx	xxx
PP analysis set	xxx	xxx	xxx
Reason for exclusion from PP analysis set*			
Received no vaccinations	x (x.x)	x (x.x)	x (x.x)
Received 1 vaccination	x (x.x)	x (x.x)	x (x.x)
Recieved 2nd vaccination outside visit window	x (x.x)	x (x.x)	x (x.x)
HIV-positive	x (x.x)	x (x.x)	x (x.x)
Inclusion/exclusion criteria not met	x (x.x)	x (x.x)	x (x.x)
Received prohibited medication	x (x.x)	x (x.x)	x (x.x)
Xxxxxx	x (x.x)	x (x.x)	x (x.x)
…			
Total	x (x.x)	x (x.x)	x (x.x)

Page 1 of x

N: Number of participants, %: Percentage of participants
** One participant can be present with more than one reason*
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

<NOTE: Will be sorted by frequency>

Table 14.1.1.5: Protocol deviations by classification and category – All randomised participants

	H56:IC31 N (%)	Placebo N (%)	Total N (%)
All randomized	xxx	xxx	xxx
Major			
Informed consent	x (x.x)	x (x.x)	x (x.x)
Eligibility criteria	x (x.x)	x (x.x)	x (x.x)
Withdrawal criteria not adhered to	x (x.x)	x (x.x)	x (x.x)
Dosing deviation	x (x.x)	x (x.x)	x (x.x)
Visit Window	x (x.x)	x (x.x)	x (x.x)
Missed procedure(s)	x (x.x)	x (x.x)	x (x.x)
Specimen deviation	x (x.x)	x (x.x)	x (x.x)
Unblinding	x (x.x)	x (x.x)	x (x.x)
Safety reporting	x (x.x)	x (x.x)	x (x.x)
Other	x (x.x)	x (x.x)	x (x.x)
Total	x (x.x)	x (x.x)	x (x.x)
Minor			
Informed consent	x (x.x)	x (x.x)	x (x.x)
⋮			
Total	x (x.x)	x (x.x)	x (x.x)
Total			
Informed consent	x (x.x)	x (x.x)	x (x.x)
⋮			
Total	x (x.x)	x (x.x)	x (x.x)

Page 1 of x

N: Number of participants, %: Percentage of participants
Protocol deviations related to Covid-19 are all deviations with wording Covid-19 or Corona. These are also included in the summary of any protocol deviations.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

<NOTE: Will be sorted by frequency>

Table 14.1.1.6: Protocol deviations related to Covid-19 by classification and category – All randomised participants

<Layout similar to table 14.1.1.5>

Table 14.1.2.1: Key demographics and baseline characteristics – ITT analysis set			
	H56:IC31	**Placebo**	**Total**
ITT analysis set	xxx	xxx	xxx
Age (years)			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx	xx - xx
Age group			
18 to 35 years	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
36 to 60 years	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Sex (N,%)			
Female	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Male	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Race (N,%)			
Asian	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Black	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
White	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Mixed cape ancestry	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Other	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Not reported	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Country (N,%)			
South Africa	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Tanzania	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Page 1 of x

N: Number of participants, %: Percentage of participants, SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.2.2: Other demographics and baseline characteristics – ITT analysis set

	H56:IC31	Placebo	Total
ITT analysis set	xxx	xxx	xxx
Height (cm)			
N	xxx	xxx	xxx
Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
Median	xxx.x	xxx.x	xxx.x
q25 - q75	xxx.x - xxx.x	xxx.x - xxx.x	xxx.x - xxx.x
Min - Max	xxx - xxx	xxx - xxx	xxx - xxx
Weight (kg)			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx	xx - xx
BMI (kg/m^2)			
N	xxx	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx	xx - xx
BMI group			
13 to 25 kg/m^2	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
25 kg/m^2 and above	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Smoking status (N,%)			
Non-smoker	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Smoker	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Ex-smoker	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Site (N,%)			
A1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
A2	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
A3	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
A4	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
A5	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
A6	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

N: Number of participants, %: Percentage of participants, SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.2.3: Additional baseline characteristics – ITT analysis set

	H56:IC31 N (%)	Placebo N (%)
ITT analysis set	xxx	xxx
Anemia		
Yes	xxx (xx.x)	xxx (xx.x)
No	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)
Diabetes mellitus		
Yes	xxx (xx.x)	xxx (xx.x)
No	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)
Comorbidity		
Yes	xxx (xx.x)	xxx (xx.x)
No	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)

N: Number of participants, %: Percentage of participants
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.2.4: Key demographics and baseline characteristics – mITT analysis set

<Layout similar to table 14.1.2.1>
<Table will not be produced if the mITT contains 90% or more of the ITT analysis set>

Table 14.1.2.5: Other demographics and baseline characteristics – mITT analysis set

<Layout similar to table 14.1.2.2>
<Table will not be produced if the mITT contains 90% or more of the ITT analysis set>

Table 14.1.2.6: Key demographics and baseline characteristics – PP analysis set

<Layout similar to table 14.1.2.1>
<Table will not be produced if the PP contains 80% or more of the ITT analysis set>

Table 14.1.2.7: Other demographics and baseline characteristics – PP analysis set

<Layout similar to table 14.1.2.2>
<Table will not be produced if the PP contains 80% or more of the ITT analysis set>

Table 14.1.3.1: Medical and surgical history by SOC and PT– ITT analysis set

	H56:IC31 N (%)	Placebo N (%)
ITT analysis set (N)	xxx	xxx
Any medical history	xxx (xxx.x)	xxx (xxx.x)
<System organ class 1>	xxx (xxx.x)	xxx (xxx.x)
<Preferred term 1>	xxx (xxx.x)	xxx (xxx.x)
<Preferred term 2>	xxx (xxx.x)	xxx (xxx.x)
...	...	...
<System organ class 2>	xxx (xxx.x)	xxx (xxx.x)
<Preferred term 1>	xxx (xxx.x)	xxx (xxx.x)
<Preferred term 2>	xxx (xxx.x)	xxx (xxx.x)
...	...	...

Page 1 of x

N: Number of participants, %: Percentage of participants.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.3.2: Medical and surgical history by SOC and PT – comorbidity terms – ITT analysis set

<Layout similar to table 14.1.3.1>

Table 14.1.3.3: Concomitant medication and new TB treatment – ITT analysis set

	H56:IC31 N (%)	Placebo N (%)
ITT analysis set (N)	xxx	xxx
Any concomitant medication	xxx (xxx.x)	xxx (xxx.x)
<Medication class 1>	xxx (xxx.x)	xxx (xxx.x)
<ATC level 4 term 1>	xxx (xxx.x)	xxx (xxx.x)
< ATC level 4 term 2>	xxx (xxx.x)	xxx (xxx.x)
...	...	...
<Medication class 2>	xxx (xxx.x)	xxx (xxx.x)
< ATC level 4 term 1>	xxx (xxx.x)	xxx (xxx.x)
< ATC level 4 term 2>	xxx (xxx.x)	xxx (xxx.x)
...	...	...

Page 1 of x

N: Number of participants, %: Percentage of participants.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.3.4: TB diagnosis and treatment history – ITT analysis set		
	H56:IC31 N (%)	**Placebo N (%)**
ITT analysis set (N)	xxx	xxx
Time from TB diagnosis to screening visit 2 (weeks)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
TB treatment		
Ethambutol	xxx (xxx.x)	xxx (xxx.x)
Isoniazid	xxx (xxx.x)	xxx (xxx.x)
Pyrazinamide	xxx (xxx.x)	xxx (xxx.x)
Rifampicin	xxx (xxx.x)	xxx (xxx.x)
Other	xxx (xxx.x)	xxx (xxx.x)
Aminobenzoic Acid	xx (xxx.x)	xx (xxx.x)
Pyridoxine	xx (xxx.x)	xx (xxx.x)
Pyridoxine Hydrochloride	xx (xxx.x)	xx (xxx.x)
Vitamin B Complex	xx (xxx.x)	xx (xxx.x)
Total	xxx (xxx.x)	xxx (xxx.x)
Time from 1st vaccination to TB treatment stop date (days)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Duration of TB treatment at screening visit 2 (weeks)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Time from completion of 22 weeks of TB treatment to screening visit 2 (days)		
N	xxx	xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Time from completion of 22 weeks of TB treatment to 1st vaccination (days)		
N	xxx	xxx

Table 14.1.3.4: TB diagnosis and treatment history – ITT analysis set		
	H56:IC31 N (%)	**Placebo N (%)**
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

Page 1 of x

N: Number of participants, %: Percentage of participants, SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.1.3.5: Exposure – safety analysis set		
	H56:IC31 N (%)	**Placebo N (%)**
Safety analysis set	xxx	xxx
Number of vaccinations		
1	x (xxx.x)	x (xxx.x)
2	xxx (xxx.x)	xxx (xxx.x)
Time from 1st to 2nd vaccination		
<46 days	x (xxx.x)	x (xxx.x)
46 - 66 days	xxx (xxx.x)	xxx (xxx.x)
>66 days	x (xxx.x)	x (xxx.x)
Time from 2nd vaccination to end of trial		
<28 days	x (xxx.x)	x (xxx.x)
28 – 91 days	xxx (xxx.x)	xxx (xxx.x)
92 – 182 days	x (xxx.x)	x (xxx.x)
183 – 273 days	x (xxx.x)	x (xxx.x)
>273 days	x (xxx.x)	x (xxx.x)
Trial duration* (days)		
N	xxx	xxx
Mean (SD)	xxx.x(xx.x)	xxx.x(xx.x)
Median	xxx.x	xxx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xxx-xxx	xxx-xxx

Page 1 of x

N: Number of participants, %: Percentage of participants, SD: Standard deviation
**Time from 1st vaccination to end of trial.*
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.1.1: Summary of TB recurrence from day 70 overall and by site – culture of sputum – mITT set

	H56:IC31 N (%)	Placebo N (%)
mITT set	xxx	xxx
TB recurrence from day 70		
All sites		
Sputum samples sent for culture*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
No recurrence	xxx (xx.x)	xxx (xx.x)
<Site A1>		
Sputum samples sent for culture*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
No recurrence	xxx (xx.x)	xxx (xx.x)
…		
<Site A6>		
Sputum samples sent for culture*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
No recurrence	xxx (xx.x)	xxx (xx.x)

N: Number of participants, %: Percentage of participants.
** Number of participants with one or more samples*
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.1.2: Primary analysis of TB recurrence from day 70 – culture of sputum – mITT set

	H56:IC31	Placebo	P-value
mITT set	xxx	xxx	
TB recurrence, N (%)			
Number of participants contributing to analysis	xxx (xx.x)	xxx (xx.x)	
TB recurrence present	xx (x.x)	xx (x.x)	
Censored without TB recurrence	xxx (xx.x)	xxx (xx.x)	
Kaplan-Meier estimates			
One sided log-rank test*			x.xxxx

**Time to TB recurrence is estimated using the Kaplan-Meier method and compared between treatment groups stratified by trial site. The objective of the trial is considered met if the p-value of the log-rank test is below 0.10.*
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.1.3: Supportive analysis of TB recurrence from day 70 – culture of sputum – mITT set

	H56:IC31	Placebo	P-value
mITT set (N)	xxx	xxx	
TB recurrence, N (%)			
TB recurrence present	xx (x.x)	xx (x.x)	
Censored without TB recurrence	xxx (xx.x)	xxx (xx.x)	
Number of participants contributing to analysis	xxx (xx.x)	xxx (xx.x)	
Kaplan-Meier estimates			
Two sided log-rank test			x.xxxx
Cox proportional hazard			
VE (%)	xx.xx		
80% PCL	(xx.xx – xx.xx)		
95% PCL	(xx.xx – xx.xx)		
Two sided likelihood ratio test			x.xxxx
Type 3 test for trial site			x.xxxx

PCL: Profile confidence limits, VE: Vaccine efficacy
The Cox proportional hazard model includes treatment and site as fixed effects.
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.1.4: Rate of TB recurrence from day 70 overall and by trial site – culture of sputum – mITT set

	H56:IC31	Placebo	Relative risk (95% CI)
mITT analysis set (N)	xx	xx	
Overall TB recurrence			
Number of participants contributing to analysis (N)	xx	xx	
Number of recurrent cases, N(%)	xx (xx.x)	xx (xx.x)	
Person years of follow-up	xxxx	xxxx	
TB recurrence incidence rate* (95% CI)	x.x (x.x – x.x)	x.x (x.x – x.x)	x.x (x.x – x.x)
Site A1			
Number of participants contributing to analysis (N)	xx	xx	
Number of recurrent cases, N(%)	xx (xx.x)	xx (xx.x)	
Person years of follow-up	xxxx	xxxx	
TB recurrence incidence rate* (95% CI)	x.x (x.x – x.x)	x.x (x.x – x.x)	x.x (x.x – x.x)
Site A2	…	…	
…			

Page 1 of x

CI: Confidence intervals, TB: Tuberculosis
**Rate per 100 person-years of follow-up*
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.1.5: Analysis of TB recurrence from day 0 – culture of sputum – ITT set

<Layout similar to table 14.2.1.2>

Table 14.2.1.6: Supportive analysis of TB recurrence from day 0 – culture of sputum – ITT set

<Layout similar to table 14.2.1.3>

Table 14.2.1.7: Rate of TB recurrence from day 0 overall and by trial site– culture of sputum – ITT set

<Layout similar to table 14.2.1.4>

Table 14.2.1.8: Analysis of TB recurrence from day 70 – culture of sputum – PP set

<Layout similar to table 14.2.1.2>

Table 14.2.1.9: Supportive analysis of TB recurrence from day 70 – culture of sputum – PP set

<Layout similar to table 14.2.1.3>

Table 14.2.1.10: Rate of TB recurrence from day 70 overall and by trial site– culture of sputum – PP set

<Layout similar to table 14.2.1.4>

Table 14.2.1.11: TB recurrence during the trial by period – culture of sputum – ITT set

	H56:IC31 N (%)	Placebo N (%)
ITT set	xxx	xxx
TB recurrence		
Sputum samples sent for culture*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
1st vaccination to 30 days post 1st vaccination	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)
Reinfection	xx (xx.x)	xx (xx.x)
Undetermined	xx (xx.x)	xx (xx.x)
31 days post 1st vaccination. to before 2nd vaccination**	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)
Reinfection	xx (xx.x)	xx (xx.x)
Undetermined	xx (xx.x)	xx (xx.x)
2nd vaccination to 14 days post 2nd vaccination	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)
Reinfection	xx (xx.x)	xx (xx.x)
Undetermined	xx (xx.x)	xx (xx.x)
15 days post 2nd vaccination to EoT	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)
Reinfection	xx (xx.x)	xx (xx.x)
Undetermined	xx (xx.x)	xx (xx.x)
Day 56 to EoT**	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)
Reinfection	xx (xx.x)	xx (xx.x)
Undetermined	xx (xx.x)	xx (xx.x)
No recurrence	xxx (xx.x)	xxx (xx.x)

Page 1 of x

N: Number of participants, %: Percentage of participants.
** Number of participants with one or more samples*
***Day 56 is used as 2nd vaccination day for subjects without 2nd vaccine*
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.1.12: Summary of TB recurrence from day 70 by number of vaccinations received – culture of sputum – mITT set

<Layout similar to table 14.2.1.1>

Table 14.2.1.13: Sensitivity analysis of TB recurrence from day 70 for participants with 2nd vaccination on day 46 to 66 – culture of sputum – mITT set

<Layout similar to table 14.2.1.2>

Table 14.2.1.14: Supportive sensitivity analysis of TB recurrence from day 70 for participants with 2nd vaccination on day 46 to 66– culture of sputum – mITT set

<Layout similar to table 14.2.1.3>

Table 14.2.1.15: Sensitivity analysis of TB recurrence from day 70 for participants with TB symptoms – culture of sputum – mITT set

<Layout similar to table 14.2.1.2>

Table 14.2.1.16: Supportive sensitivity analysis of TB recurrence from day 70 excluding sputum samples taken without TB symptoms or positive Expert MTB/RIF Ultra – culture of sputum – mITT set

<Layout similar to table 14.2.1.3>

Table 14.2.1.17: Analysis of TB recurrence from day 70 by trial site – culture of sputum – mITT set

	TB recurrence n/N (%)	H56:IC31 vs. Placebo VE (%) (95% PCL)	P-value
mITT set	xxx		
Site			
A1			
H56:IC31	xx/xxx (xx.x)	xx.xx (xx.xx – xx.xx)	
Placebo	xx/xxx (xx.x)		
A2			
H56:IC31	xx/xxx (xx.x)	xx.xx (xx.xx – xx.xx)	
Placebo	xx/xxx (xx.x)		
.			
.			
.			
Joint test for interaction			x.xxxx

Page 1 of x

N: Number of participants, n: number of participants with TB recurrence, PCL: Profile confidence limits, VE: Vaccine efficacy. The estimates are from a Cox proportional hazard model with treatment, trial site and treatment times trial site interaction as fixed effects.

Day 70 is interpreted as 2nd vaccination + 14 days.

Trial: <Trial id>

Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.1.18: Analysis of TB recurrence from day 70 by country– culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.19: Analysis of TB recurrence from day 70 by BMI group – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.20: Analysis of TB recurrence from day 70 by age group – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.21: Analysis of TB recurrence from day 70 by sex – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.22: Analysis of TB recurrence from day 70 by smoking status – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.23: Analysis of TB recurrence from day 70 by anemia – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.24: Analysis of TB recurrence from day 70 by diabetes mellitus – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.25: Analysis of TB recurrence from day 70 by comorbidity at baseline – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.26: Analysis of TB recurrence from day 70 by use of steroids and anti-inflammatory drugs – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.27: Analysis of TB recurrence from day 70 by number of vaccinations – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.28: Analysis of TB recurrence from day 70 by Covid-19 relevant PDs – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>

Table 14.2.1.29: Analysis of TB recurrence from day 70 by corona virus infection – culture of sputum – mITT set

<Layout similar to table 14.2.1.17>
<NOTE: Will only be presented if at least 5 subjects have an event>

Table 14.2.2.1: Summary of SNP and allele distances by recurrence and overall – WGS – mITT set

	H56:IC31	Placebo
mITT set	xxx	xxx
Reinfection		
SNP distance		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Allele distance		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Relapse		
SNP distance		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Allele distance		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Overall		
SNP distance		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
SNP distance (N,%)		
0<= SNP <=5	xx (xx.x)	xx (xx.x)
5< SNP <=12	xx (xx.x)	xx (xx.x)
SNP > 12	xx (xx.x)	xx (xx.x)

Table 14.2.2.1: Summary of SNP and allele distances by recurrence and overall – WGS – mITT set		
	H56:IC31	**Placebo**
Allele distance		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Allele distance		
0<= allele <=5	xx (xx.x)	xx (xx.x)
5< allele <=12	xx (xx.x)	xx (xx.x)
allele > 12	xx (xx.x)	xx (xx.x)

N: Number of participants, SD: standard deviation, q25: Lower quartile, q75: Upper quartile
The distance between the screening visit sample and the recurrence visit sample is presented
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.2.2: Analysis of TB relapse from day 70 – culture of sputum and WGS – mITT set			
	H56:IC31	**Placebo**	**P-value**
mITT set	xxx	xxx	
Summary, N (%)			
TB relapse	xx (x.x)	xx (x.x)	
Censored without TB relapse	xxx (xx.x)	xxx (xx.x)	
Number of participants contributing to analysis	xxx (xx.x)	xxx (xx.x)	
Cox proportional hazard			
VE (%)	xx.xx		
80% PCL	(xx.xx – xx.xx)		
95% PCL	(xx.xx – xx.xx)		
Two-sided likelihood ratio test			x.xxxx
Type 3 test for trial site			x.xxxx

PCL: Profile confidence limits, VE: Vaccine efficacy
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.2.3: Rate of TB relapse from day 70 overall and by trial site – culture of sputum and WGS – mITT set

	H56:IC31	Placebo	Relative risk (95% CI)
mITT analysis set	xxx	xxx	
Number of participants	xx	xx	
Number of relapse cases	xx	xx	
Person years of follow-up	xxxx	xxxx	
TB relapse incidence rate* (95% CI)	x.x (x.x – x.x)	x.x (x.x – x.x)	x.x (x.x – x.x)
<Site A1>			
Number of participants	xx	xx	
Number of relapse cases	xx	xx	
Person years of follow-up	xxxx	xxxx	
TB relapse incidence rate* (95% CI)	x.x (x.x – x.x)	x.x (x.x – x.x)	x.x (x.x – x.x)
⋮			
<Site A6>			

Page 1 of x

CI: Confidence intervals
1) Rate per 100 person-years of follow-up
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.2.4: Summary of SNP and allele distances by recurrence and overall – WGS – ITT set

<Layout similar to table 14.2.2.1>

Table 14.2.2.5: Analysis of TB relapse from day 0 – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.2.2>

Table 14.2.2.6: Rate of TB relapse from day 0 overall and by trial site – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.2.3>

Table 14.2.3.1: Analysis of TB reinfection from day 70 – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.2.2>

Table 14.2.3.2: Rate of TB reinfection from day 70 overall and by trial site – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.2.3>

Table 14.2.3.3: Analysis of TB reinfection from day 0 – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.2.2>

Table 14.2.3.4: Rate of TB reinfection from day 0 overall and by trial site – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.2.3>

Table 14.2.4.1: Summary of TB recurrence type from day 70 overall and by trial site – culture of sputum and WGS – mITT set

	H56:IC31 N (%)	Placebo N (%)
mITT set	xxx	xxx
TB recurrence from day 70*		
Sputum samples sent for culture*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)
Reinfection	xx (xx.x)	xx (xx.x)
Undetermined	xx (xx.x)	xx (xx.x)
No recurrence	xxx (xx.x)	xxx (xx.x)
<Site A1>		
Sputum samples sent for culture*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)
Reinfection	xx (xx.x)	xx (xx.x)
Undetermined	xx (xx.x)	xx (xx.x)
No recurrence	xxx (xx.x)	xxx (xx.x)
…		
<Site A6>		
Sputum samples sent for culture*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
…		

N: Number of participants, %: Percentage of participants.
WGS: Whole genome sequencing
Day 70 is interpreted as 2nd vaccination + 14 days.
** Number of participants with one or more samples*
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.4.2: Summary of TB recurrence type from day 70 overall and by country– culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.3: Summary of TB recurrence type from day 70 overall and by BMI group– culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.4: Summary of TB recurrence type from day 70 overall and by age group – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.5: Summary of TB recurrence type from day 70 overall and by sex – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.6: Summary of TB recurrence type from day 70 overall and by smoking status – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.7: Summary of TB recurrence type from day 70 overall and by anemia – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.8: Summary of TB recurrence type from day 70 overall and by diabetes mellitus – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.9: Summary of TB recurrence type from day 70 overall and by comorbidity at baseline – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.10: Summary of TB recurrence type from day 70 overall and by use of steroids and anti-inflammatory drugs – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.11: Summary of TB recurrence type from day 70 overall and by number of vaccinations – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.12: Summary of TB recurrence type from day 70 overall and by Covid-19 relevant PDs – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.13: Summary of TB recurrence type from day 70 overall and by corona virus infection – culture of sputum and WGS – mITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.14: Summary of TB recurrence type from day 0 overall and by trial site– culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.15: Summary of TB recurrence type from day 0 overall and by country– culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.16: Summary of TB recurrence type from day 0 overall and by BMI group– culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.17: Summary of TB recurrence type from day 0 overall and by age group – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.18: Summary of TB recurrence type from day 0 overall and by sex – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.19: Summary of TB recurrence type from day 0 overall and by smoking status – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.20: Summary of TB recurrence type from day 0 overall and by anemia – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.21: Summary of TB recurrence type from day 0 overall and by diabetes mellitus – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.22: Summary of TB recurrence type from day 0 overall and by comorbidity at baseline – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.23: Summary of TB recurrence type from day 0 overall and by use of steroids and anti-inflammatory drugs – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.24: Summary of TB recurrence type from day 0 overall and by number of vaccinations – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.25: Summary of TB recurrence type from day 0 overall and by Covid-19 relevant PDs – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.4.26: Summary of TB recurrence type from day 0 overall and by corona virus infection – culture of sputum and WGS – ITT set

<Layout similar to table 14.2.4.1>

Table 14.2.5.1: H56 protein-specific CD4⁺ T-cells expressing any combination of IL-2, IFN- γ, TNF-α or IL-17 (%) – WB ICS – Immunogenicity analysis set

	H56:IC31	Placebo
Immunogenicity analysis set (N)	xx	xx
Total cytokine response (%)		
Visit 3 (Day 0) - Baseline		
N	xx	xx
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 6 (Day 70)		
N	xx	xx
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Change from Baseline to Visit 6 (Day 70)		
N	xx	xx
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

Page 1 of x

N: Number of participants, SD: standard deviation, q25: Lower quartile, q75: Upper quartile

Antigen specific CD4⁺ T cells expressing any of the cytokines, IL-2, IFN-γ, TNF-α, or IL-17 after stimulation with H56

Trial: <Trial id>

Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.5.2: H56 protein-specific CD4⁺ T-cells expressing any combination of IL-2, IFN- γ, TNF-α or IL-17 (%) – WB ICS – Immunogenicity cohort

<Layout similar to table 14.2.5.1>

Table 14.2.5.3: H56 protein-specific CD4⁺ T-cells co-expressing IL-2, IFN- γ, and TNF-α (%) – WB ICS – Immunogenicity analysis set

<Layout similar to table 14.2.5.1>

Table 14.2.5.4: H56 protein-specific CD4⁺ T-cells co-expressing IL-2, IFN- γ, and TNF-α (%) – WB ICS – Immunogenicity analysis set

<Layout similar to table 14.2.5.1>

Table 14.2.5.5: H56 protein-specific CD4⁺ T-cells co-expressing IL-2 and TNF-α (%) – WB ICS – Immunogenicity analysis set

<Layout similar to table 14.2.5.1>

Table 14.2.5.6: H56 protein-specific CD4⁺ T-cells co-expressing IL-2 and TNF-α (%) – WB ICS – Immunogenicity cohort

<Layout similar to table 14.2.5.1>

Table 14.2.5.7: H56 protein-specific CD8⁺ T-cells expressing any combination of IL-2, IFN- γ, TNF-α or IL-17 (%) – WB ICS – Immunogenicity analysis set

<Layout similar to table 14.2.5.1>

Table 14.2.5.8: H56 protein-specific $CD8^+$ T-cells expressing any combination of IL-2, IFN- γ, TNF-α or IL-17 (%) – WB ICS – Immunogenicity cohort

<Layout similar to table 14.2.5.1>

Table 14.2.6.1: Humoral immune responses by IgG ELISA – Immunogenicity analysis set

	H56:IC31	Placebo
Immunogenicity analysis set, N	xx	xx
Anti-H56 IgG (EU/mL)		
Visit 3 (Day 0) - Baseline		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 6 (Day 70)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Fold increase from Baseline to Visit 6 (Day 70)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

Page 1 of x

N: Number of participants, SD: standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.6.2: Humoral immune responses by IgG ELISA – Immunogenicity cohort

<Layout similar to table 14.2.6.1>

Table 14.2.7.1: TB recurrence from day 70 – culture of sputum or new TB treatment – mITT set

	H56:IC31 N (%)	Placebo N (%)
mITT set (N)	xxx	xxx
TB recurrence		
Recurrence	xx (xx.x)	xx (xx.x)
Started TB treatment without confirmation	xx (xx.x)	xx (xx.x)
Culture confirmed	xx (xx.x)	xx (xx.x)
No recurrence*	xxx (xx.x)	xxx (xx.x)
Total	xxx (xx.x)	xxx (xx.x)

N: Number of participants, %: Percentage of participants.
Day 70 is interpreted as 2nd vaccination + 14 days.
** Number of participants with one or more samples*
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.7.2: Analysis of TB recurrence from day 70 – culture of sputum or new TB treatment – mITT set

	H56:IC31	Placebo	P-value
Summary, N (%)			
TB recurrence	xx (x.x)	xx (x.x)	
Censored without TB recurrence	xxx (xx.x)	xxx (xx.x)	
Number of participants contributing to analysis	xxx (xx.x)	xxx (xx.x)	
Cox proportional hazard			
VE (%)	xx.xx		
80% PCL	(xx.xx – xx.xx)		
95% PCL	(xx.xx – xx.xx)		
Two sided likelihood ratio test			x.xxxx
Type 3 test for trial site			x.xxxx

PCL: Profile confidence limits, VE: Vaccine efficacy
The estimates are from a Cox proportional hazard model with treatment and site as fixed effects.
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.7.3: Sensitivity analysis of TB recurrence from day 70 – culture of sputum or new TB treatment – mITT set

	H56:IC31	Placebo	P-value
mITT set, N	xxx	xxx	
TB recurrence (N,%)			
Number of participants contributing to analysis	xxx (x.x)	xxx (x.x)	
TB recurrence present	xxx (x.x)	xxx (x.x)	
Censored without TB recurrence	xxx (x.x)	xxx (x.x)	
Cox proportional hazard*			
VE (%)	xx.xx		
80% PCL	(xx.xx – xx.xx)		
95% PCL	(xx.xx – xx.xx)		
Two sided likelihood ratio test			x.xxxx
Type 3 test for country			x.xxxx

PCL: Profile confidence limits, VE: Vaccine efficacy
**The estimates are from a Cox proportional hazard model with treatment and country as fixed effects.*
Day 70 is interpreted as 2nd vaccination + 14 days.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.7.4: Rate of TB recurrence from day 70 overall and by trial site – culture of sputum or new TB treatment – mITT set

<Layout similar to table 14.2.2.3>

Table 14.2.7.5: TB recurrence from day 0 – culture of sputum or new TB treatment – ITT set

<Layout similar to table 14.2.7.1>

Table 14.2.7.6: Analysis of TB recurrence from day 0 – culture of sputum or new TB treatment – ITT set

<Layout similar to table 14.2.7.2>

Table 14.2.7.7: Rate of TB recurrence from day 0 overall and by trial site – culture of sputum or new TB treatment – ITT set

<Layout similar to table 14.2.2.3>

Table 14.2.8.1: TB recurrence from day 70 – Xpert MTB/RIF Ultra or culture of sputum – mITT set

	H56:IC31 N (%)	Placebo N (%)
mITT set (N)	xxx	xxx
TB recurrence		
Sputum samples collected*	xx (xx.x)	xx (xx.x)
Recurrence	xx (xx.x)	xx (xx.x)
By Xpert only	xx (xx.x)	xx (xx.x)
By Xpert and culture	xx (xx.x)	xx (xx.x)
By culture only	xx (xx.x)	xx (xx.x)
No recurrence	xxx (xx.x)	xxx (xx.x)
total	xxx (xx.x)	xxx (xx.x)

Page 1 of x

N: Number of participants, %: Percentage of participants.
Day 70 is interpreted as 2nd vaccination + 14 days.
** Number of participants with one or more samples*
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.2.8.2: Analysis of TB recurrence from day 70 – Xpert MTB/RIF Ultra or culture of sputum – mITT set

<Layout similar to table 14.2.7.2>

Table 14.2.8.3: Sensitivity analysis of TB recurrence from day 70 – Xpert MTB/RIF Ultra or culture of sputum – mITT set

<Layout similar to table 14.2.7.3>

Table 14.2.8.4: Rate of TB recurrence from day 70 overall and by trial site – Xpert MTB/RIF Ultra or culture of sputum – mITT set

<Layout similar to table 14.2.2.3>

Table 14.2.8.5: TB recurrence from day 0 – Xpert MTB/RIF Ultra or culture of sputum – ITT set

<Layout similar to table 14.2.7.1>

Table 14.2.8.6: Analysis of TB recurrence from day 0 – Xpert MTB/RIF Ultra or culture of sputum – ITT set

<Layout similar to table 14.2.7.2>

Table 14.2.8.7: Rate of TB recurrence from day 0 overall and by trial site – Xpert MTB/RIF Ultra or culture of sputum – ITT set

<Layout similar to table 14.2.2.3>

Table 14.2.9.1: TB recurrence during the trial by period – culture of sputum – mITT2 set

<Layout similar to table 14.2.1.11>

Table 14.2.9.2: Analysis of TB recurrence from day 30 – culture of sputum – mITT2 set

<Layout similar to table 14.2.7.2>

Table 14.2.9.3: Sensitivity analysis of TB recurrence from day 30 – culture of sputum – mITT2 set

<Layout similar to table 14.2.7.3>

Table 14.2.9.4: Rate of TB recurrence from day 30 overall and by trial site – culture of sputum – mITT2 set

<Layout similar to table 14.2.2.3>

Table 14.3.1.1: Summary of adverse events – safety analysis set

	H56:IC31 N (%) E	Placebo N (%) E
	xxx	xxx
Safety analysis set (N)		
Any adverse event	xx (xx.x) xx	xx (xx.x) xx
Solicited AE	xx (xx.x) xx	xx (xx.x) xx
AESI	xx (xx.x) xx	xx (xx.x) xx
SAE	xx (xx.x) xx	xx (xx.x) xx
Fatal AE	xx (xx.x)	xx (xx.x)
Related AE	xx (xx.x) xx	xx (xx.x) xx
Related SAE	xx (xx.x) xx	xx (xx.x) xx
SUSAR	xx (xx.x) xx	xx (xx.x) xx
AE leading to discontinuation of IMP	xx (xx.x) xx	xx (xx.x) xx
AE leading to discontinuation of trial	xx (xx.x) xx	xx (xx.x) xx
Intensity		
Severe	xx (xx.x) xx	xx (xx.x) xx
Moderate	xx (xx.x) xx	xx (xx.x) xx
Mild	xx (xx.x) xx	xx (xx.x) xx
Outcome		
Fatal	xx (xx.x) xx	xx (xx.x) xx
Not yet recovered	xx (xx.x) xx	xx (xx.x) xx
Recovered with sequelae	xx (xx.x) xx	xx (xx.x) xx
Recovered without sequelae	xx (xx.x) xx	xx (xx.x) xx
Unknown	xx (xx.x) xx	xx (xx.x) xx

Page 1 of x

N: Number of participants, %: Percentage of participants, E: Number of events.
Only treatment emergent AEs are presented, Solicited AEs:Events occurring within 7 days after a vaccination and of the following types: the injection site reactions redness, swelling, and tenderness/pain, and the systemic adverse events fever, arthralgia, myalgia, fatigue, headache, rash, chills, and nausea. AESI: Adverse event of special interest,
SAE: Serious adverse event, SUSAR: Suspected unexpected serious adverse reaction
Trial: <Trial id>
Program: <program_name>.sas – output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.1.2: Adverse events by SOC and preferred term – safety analysis set

	H56:IC31 N (%) E	Placebo N (%) E
Safety analysis set (N)	xxx	xxx
Any adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
<System organ class 2>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...

Page 1 of x

N: Number of participants, %: Percentage of participants, E: Number of events, SOC: System organ class
Sorted by total frequency of participants, total frequency of events, SOC, and preferred term.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.1.3: Summary of solicited adverse events within 7 days after vaccination – safety analysis set

<Layout similar to table 14.3.1.1>

Table 14.3.1.4: Solicited adverse events within 7 days after vaccination by SOC and preferred term– safety analysis set

<Layout similar to table 14.3.1.2>

Table 14.3.1.5: Summary of unsolicited adverse events within 14 days after vaccination – safety analysis set

<Layout similar to table 14.3.1.1>

Table 14.3.1.6: Unsolicited adverse events within 14 days after vaccination by SOC and preferred term – safety analysis set

<Layout similar to table 14.3.1.2>

Table 14.3.1.7: Adverse events within 14 days after vaccination by severity, SOC and preferred term – safety analysis set

	H56:IC31 N (%) E	Placebo N (%) E
Safety analysis set (N)	xxx	xxx
Any severe adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
<System organ class 2>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
Any moderate adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
Any mild adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
...	...	...

Page 1 of x

AEs occurring within the first 14 days after each of the two vaccinaitions are included.
N: Number of participants, %: Percentage of participants, E: Number of events, SOC: System organ class
Sorted by severity, total frequency of participants, total frequency of events, SOC, and preferred term.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.1.8: Adverse events within 14 days after vaccination by causality, SOC and preferred term – safety analysis set

	H56:IC31 N (%) E	Placebo N (%) E
Safety analysis set (N)	xxx	xxx
Any related adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
<System organ class 2>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
Any not related adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
...	...	...

AEs occurring within the first 14 days after each of the two vaccinations are included..
N: Number of participants, %: Percentage of participants, E: Number of events, SOC: System organ class
Sorted by causality, total frequency of participants, total frequency of events, SOC, and preferred term.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.1.9: Adverse events within 14 days after vaccination by age group, SOC, and preferred term – safety analysis set

	H56:IC31 N (%) E	Placebo N (%) E
Safety analysis set (N)	xxx	xxx
Participants 18-35 years		
Any adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
<System organ class 2>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 2>	xx (xx.x) xx	xx (xx.x) xx
...	...	...
Participants >35 years		
Any adverse event	xx (xx.x) xx	xx (xx.x) xx
<System organ class 1>	xx (xx.x) xx	xx (xx.x) xx
<Preferred term 1>	xx (xx.x) xx	xx (xx.x) xx
...	...	...

Page 1 of x

AEs occurring within the first 14 days after each of the two vaccinations are included.
N: Number of participants, %: Percentage of participants, E: Number of events, SOC: System organ class
Sorted by age group, total frequency of participants, total frequency of events, SOC, and preferred term.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.1.10: Adverse events within 14 days after vaccination by sex, SOC, and preferred term – safety analysis set

<Layout similar to table 14.3.1.7>

Table 14.3.1.11: Summary of adverse events of special interest – safety analysis set

<Layout similar to table 14.3.1.1>

Table 14.3.1.12: Adverse events of special interest by SOC and preferred term – safety analysis set

<Layout similar to table 14.3.1.2>

Table 14.3.1.13: Summary of serious adverse events – safety analysis set

<Layout similar to table 14.3.1.1>
<NOTE: SAEs including medically important events>

Table 14.3.1.14: Serious adverse events by SOC and preferred term – safety analysis set

<Layout similar to table 14.3.1.1>
<NOTE: SAEs including medically important events>

Table 14.3.1.15: Summary of solicited serious adverse events within 7 days after vaccination – safety analysis set

<Layout similar to table 14.3.1.1>
<NOTE: SAEs including medically important events>

Table 14.3.1.16: Solicited serious adverse events within 7 days after vaccination by SOC and preferred term – safety analysis set

<Layout similar to table 14.3.1.2>
<NOTE: SAEs including medically important events>

Table 14.3.1.17: Summary of unsolicited serious adverse events within 14 days after vaccination – safety analysis set

<Layout similar to table 14.3.1.1>
<NOTE: SAEs including medically important events>

Table 14.3.1.18: Unsolicited serious adverse events within 14 days after vaccination by SOC and preferred term – safety analysis set

<Layout similar to table 14.3.1.1>
<NOTE: SAEs including medically important events>

Table 14.3.1.19: Summary of adverse events within 14 days after vaccination – safety analysis set

<Layout similar to table 14.3.1.1>

Table 14.3.1.20: Adverse events within 14 days after vaccination by SOC and preferred term – safety analysis set

<Layout similar to table 14.3.1.1>

Table 14.3.2.1: Injection site reactions and axillary lymphadenopathy within 14 days after vaccination by period – safety analysis set

	H56:IC31 N (%) E	Placebo N (%) E
Safety analysis set (N)	xxx	xxx
Day 0: 1st vaccination		
Redness	xx (xx.x) xx	xx (xx.x) xx
Swelling	xx (xx.x) xx	xx (xx.x) xx
Tenderness/pain	xx (xx.x) xx	xx (xx.x) xx
Other	xx (xx.x) xx	xx (xx.x) xx
Axillary lymphadenopathy	xx (xx.x) xx	xx (xx.x) xx
Day 1 to 7 after 1st vaccination		
Redness	xx (xx.x) xx	xx (xx.x) xx
Swelling	xx (xx.x) xx	xx (xx.x) xx
Tenderness/pain	xx (xx.x) xx	xx (xx.x) xx
Other	xx (xx.x) xx	xx (xx.x) xx
Axillary lymphadenopathy	xx (xx.x) xx	xx (xx.x) xx
Day 8 to 14 after 1st vaccination		
Redness	xx (xx.x) xx	xx (xx.x) xx
Swelling	xx (xx.x) xx	xx (xx.x) xx
Tenderness/pain	xx (xx.x) xx	xx (xx.x) xx
Other	xx (xx.x) xx	xx (xx.x) xx
Axillary lymphadenopathy	xx (xx.x) xx	xx (xx.x) xx
Day 56: 2nd vaccination		
Redness	xx (xx.x) xx	xx (xx.x) xx
Swelling	xx (xx.x) xx	xx (xx.x) xx
Tenderness/pain	xx (xx.x) xx	xx (xx.x) xx
Other	xx (xx.x) xx	xx (xx.x) xx
Axillary lymphadenopathy	xx (xx.x) xx	xx (xx.x) xx
Day 1 to 7 after 2nd vaccination		
Redness	xx (xx.x) xx	xx (xx.x) xx
Swelling	xx (xx.x) xx	xx (xx.x) xx
Tenderness/pain	xx (xx.x) xx	xx (xx.x) xx
Other	xx (xx.x) xx	xx (xx.x) xx
Axillary lymphadenopathy	xx (xx.x) xx	xx (xx.x) xx
Day 8 to 14 after 2nd vaccination		
Redness	xx (xx.x) xx	xx (xx.x) xx
Swelling	xx (xx.x) xx	xx (xx.x) xx
Tenderness/pain	xx (xx.x) xx	xx (xx.x) xx
Other	xx (xx.x) xx	xx (xx.x) xx
Axillary lymphadenopathy	xx (xx.x) xx	xx (xx.x) xx

N: Number of participants, %: Percentage of participants
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.2.2: Summary of solicited injection site reactions within 7 days after vaccination– safety analysis set

<Layout similar to table 14.3.1.1>

Table 14.3.2.3: Maximum diameter of redness (mm) within 7 days after vaccination – safety analysis set

	H56:IC31	Placebo
Safety analysis set (N)	xxx	xxx
Max diameter of redness (mm)		
Day 0: 1st vaccination		
E	xx	xx
Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)
Median	xxx.x	xxx.x
q25 - q75	xxx.x - xxx.x	xxx.x - xxx.x
Min - Max	xxx - xxx	xxx - xxx
Day 1 to 7 after 1st vaccination		
E	xx	x
Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)
Median	xxx.x	xxx.x
q25 - q75	xxx.x - xxx.x	xxx.x - xxx.x
Min - Max	xxx - xxx	xxx - xxx
Day 56: 2nd vaccination		
E	xx	xx
Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)
Median	xxx.x	xxx.x
q25 - q75	xxx.x - xxx.x	xxx.x - xxx.x
Min - Max	xxx - xxx	xxx - xxx
Day 1 to 7 after 2nd vaccination		
E	xx	xx
Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)
Median	xxx.x	xxx.x
q25 - q75	xxx.x - xxx.x	xxx.x - xxx.x
Min - Max	xxx - xxx	xxx - xxx

Page 1 of x

E: Number of reactions with non-missing measurement of size.
SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.2.4: Maximum diameter of size of swelling (mm) within 7 days after vaccination – safety analysis set

<Layout similar to table 14.3.2.3>

Table 14.3.2.5: Summary of solicited systemic reactions within 7 days after vaccination – safety analysis set

<Layout similar to table 14.3.1.1>

Table 14.3.2.6: Maximum temperature measurement (°C) within 7 days after vaccination – safety analysis set

<Layout similar to table 14.3.2.4>

Table 14.3.3.1: Vital signs – Systolic blood pressure (mmHg) by visit – Safety analysis set

	H56:IC31	Placebo
Safety analysis set (N)	xx	xx
Systolic blood pressure (mmHg)		
Visit 2 - Screening		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 3 (Day 0) - Baseline		
Pre-vaccination		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Post-vaccination		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Change from Pre- to Post-vaccination		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 4 (Day 14)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 5 (Day 56)		
Pre-vaccination		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

Table 14.3.3.1: Vital signs – Systolic blood pressure (mmHg) by visit – Safety analysis set		
	H56:IC31	**Placebo**
Post-vaccination		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Change from Pre- to Post-vaccination		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 6 (Day 70)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Early termination visit		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

N: Number of participants, SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.3.2: Vital signs – Diastolic blood pressure (mmHg) by visit – Safety analysis set

<Layout similar to table 14.3.3.1>

Table 14.3.3.3: Vital signs – Pulse (bpm) by visit – Safety analysis set

<Layout similar to table 14.3.3.1>

Table 14.3.3.4: Vital signs – Axillary temperature (ºC) by visit – Safety analysis set

<Layout similar to table 14.3.3.1>

Table 14.3.3.5: Body weight (kg) by visit – Safety analysis set		
	H56:IC31	**Placebo**
Safety analysis set (N)	xx	xx
Body weight (kg)		
Visit 1 - Screening		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 2 – Screening		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min – Max	xx - xx	xx - xx
Visit 3 - Baseline		
…	…	
…		
Visit 8 (Day 421)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Early termination visit		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

Page 1 of x

N: Number of participants, SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.3.6: Change from baseline in body weight (kg) by visit – Safety analysis set		
	H56:IC31	**Placebo**
Safety analysis set (N)	xx	xx
Change in body weight (Kg)		
Visit 4 (Day 14)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 5 (Day 56)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 6 (Day 70)		
…		
…		
Early termination visit		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

Page 1 of x

N: Number of participants, SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.4: TB symptoms by visit – Safety analysis set

	H56:IC31 N (%)	Placebo
Safety analysis set (N)	xx	xx
TB symptoms		
Visit 4 (Day 14)		
Any signs or symptoms	xx (xx.x)	xx (xx.x)
Unexplained cough for longer than two weeks	xx (xx.x)	xx (xx.x)
Fever	xx (xx.x)	xx (xx.x)
Night sweats	xx (xx.x)	xx (xx.x)
Loss of weight	xx (xx.x)	xx (xx.x)
Hemoptysis	xx (xx.x)	xx (xx.x)
Other symptoms	xx (xx.x)	xx (xx.x)
Visit 5 (Day 56)		
Any signs or symptoms	xx (xx.x)	xx (xx.x)
Unexplained cough …	xx (xx.x)	xx (xx.x)
….	…	

Page 1 of x

N: Number of participants, %: Percentages of participants.
Visits include scheduled visits and unscheduled visits occurring before next scheduled visit.
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.5.1: Biochemistry – AST (µKat/L) by visit – Safety analysis set		
	H56:IC31	**Placebo**
Safety analysis set (N)	xx	xx
AST (µKat/L)		
Visit 2 - Screening		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 4 (Day 14)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Visit 6 (Day 70)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx
Early termination visit		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
q25 - q75	xx.x - xx.x	xx.x - xx.x
Min - Max	xx - xx	xx - xx

AST: Aspartate Aminotransferase
N: Number of participants, SD: Standard deviation, q25: Lower quartile, q75: Upper quartile
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.5.2: Biochemistry – ALT (µKat/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.3: Biochemistry – ALP (µKat/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.4: Biochemistry – ALT (µKat/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.5: Biochemistry – GGT (µKat/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.6: Biochemistry – Total bilirubin (µmol/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.7: Biochemistry – Creatinine (μmol/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.8: Hematology – Hemaglobin (g/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.9: Hematology – Hematocrrit (L/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.10: Hematology – Leukocytes (10^9/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.11: Hematology – Lymphocytes (10^9/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.12: Hematology – Monocytes (10^9/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.13: Hematology – Neutrophils (10^9/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.14: Hematology – Basophils (10^9/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.15: Hematology – Eosinophils (10^9/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.16: Hematology – Platelets (10^9/L) by visit – Safety analysis set

<Layout similar to table 14.3.5.1>

Table 14.3.5.17: Urinalysis – Protein by visit – Safety analysis set

	H56:IC31 N (%)	Placebo N (%)
Safety analysis set (N)	xx	xx
Protein		
Visit 2 - Screening		
None	xx (xx.x)	xx (xx.x)
Trace	xx (xx.x)	xx (xx.x)
1+	xx (xx.x)	xx (xx.x)
2+	xx (xx.x)	xx (xx.x)
3+	xx (xx.x)	xx (xx.x)
>=4+	xx (xx.x)	xx (xx.x)
Positive	xx (xx.x)	xx (xx.x)
Negative	xx (xx.x)	xx (xx.x)
Small	xx (xx.x)	xx (xx.x)
Moderate	xx (xx.x)	xx (xx.x)
Large	xx (xx.x)	xx (xx.x)
20 mg/dL	xx (xx.x)	xx (xx.x)
30 mg/dL	xx (xx.x)	xx (xx.x)
100 mg/dL	xx (xx.x)	xx (xx.x)
500 mg/dL	xx (xx.x)	xx (xx.x)
Not Done	xx (xx.x)	xx (xx.x)
Total	xxx (xxx)	xxx (xxx)
Visit 4 (Day 14)		
None	xx (xx.x)	xx (xx.x)
Trace	xx (xx.x)	xx (xx.x)
1+	xx (xx.x)	xx (xx.x)
...		
Visit 6 (Day 70)		
None	xx (xx.x)	xx (xx.x)
Trace	xx (xx.x)	xx (xx.x)
1+	xx (xx.x)	xx (xx.x)
...		
Early termination visit		
None	xx (xx.x)	xx (xx.x)
Trace	xx (xx.x)	xx (xx.x)
1+	xx (xx.x)	xx (xx.x)
...		

N: Number of participants, %: Procentages of participants
Trial: <Trial id>
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Table 14.3.5.18: Urinalysis – Glucose by visit – Safety analysis set

<Layout similar to table 14.3.5.17>

Table 14.3.5.19: Urinalysis – Leukocytes by visit – Safety analysis set

<Layout similar to table 14.3.5.17>

Table 14.3.5.20: Urinalysis – Erythrocytes by visit – Safety analysis set

<Layout similar to table 14.3.5.17>

Listing shells

Listing 16.1.7.1: Participant randomisation – ITT analysis set

Site/ Paticipant id	Randomisation number	Assigned treatment	Safety cohort	Block id	Date of randomisation
A1 / Axxxxx	xxxx	Xxxxxxxxx	Yes	xxx	ddmmmyyyy
A1 / Axxxxx	xxxx	xxxxxxxxxx	Yes	xxx	ddmmmyyyy

Listing 16.2.1.1: Screening failures – All screened participants

Site/ Participant id	Rando-mised (Y/N)	Screening date	Reason	Criterion no.	Violated criterion / Other specification
A1 / Axxxxx	Y	Ddmmmyyyy	Exclusion	Xx	Xxxxxxxxx
A1 / Axxxxx	N	ddmmmyyyy	Inclusion	xx	Xxxxxxxxxx xxxxxx
		ddmmmyyyy	Other		Xxxxxxxxxx xxxxxx

Listing 16.2.1.2: Participant disposition – ITT analysis set

Site/ Participant id	Treatment	Date of consent	Analysis set (Y/N)		Reason for exclusion from PP		Immuno-genicity cohort
			mITT/ mITT2/ PP /ITT	Safety/ Immunogenicity			
A1 / Axxxxx	Xxxxx	ddmmmyyyy	Y/Y/Y/Y	Y/Y			Y
A1 / Axxxxx	Xxxxxx	ddmmmyyyy	Y/Y/N/Y	Y/Y	xxxxxxxxxxx		Y

ITT: Intention to treat, mITT: Modified ITT, mITT2: Second modified ITT, PP: Per protocol,
Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.1.3: Reason for withdrawal from trial – ITT analysis set

Site/ Participant id	Treatment	Date of randomization	End of trial date	Reason for withdrawal	Specification
A1 / Axxxxx	Xxxxx	ddmmmyyyy	ddmmmyyyy	Lost to follow-up	
A1 / Axxxxx	Xxxxxx	ddmmmyyyy	ddmmmyyyy	Withdrawal by participant	
A1 / Axxxxx	Xxxxxx	ddmmmyyyy	ddmmmyyyy	Other	Xxxxxxxxxxx xxx

Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.2: Protocol deviations – All randomised participants

Site/ Participant id	Treatment	Related visit	Deviation category	Other specification	Deviation description	Major/Leading to exclusion from PP (Y/N)
A1 / Axxxxx	Xxxxx	Visit x	Visit window	Covid-19	Xxxxxxxxxx	Y/N
A1 / Axxxxx	Xxxxxx		xxxxxxx		xxxxxxxxxxxxxxxxxxxxxxxxxxxx	N/N

Major as captured in the eCRF
Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.4.1: Demographics and baseline characteristics – ITT analysis set

Site/ Participant id	Treatment	Country	Age (years)	Sex	Race	Smoking Status	No. of cigarettes per day	Years of smoking	Smoking end date	Weight (kg)	Height (cm)	BMI (kg/m2)
A1 / Axxxxx	Xxxxx	Xxxxx xxxxx	Xx	Xxxx	xxxxx	Xxxxxx	Xx	Xx	ddmmmyyyy	xx	xxx	xx.x
A1 / Axxxxx	xxxxx	Xxxxx xxxxx	xx	xxxxxx	xxxxx	xxxxxx	Xx	xx		Xx	Xxx	xx.x

Trial: POR A-055
Program: <program>.sas – output: <output>.rtf – executed: DDMMMYYYY

Listing 16.2.4.2: Additional baseline characteristics – ITT analysis set

Site/Participant id	Treatment	Anemia	Diabetes mellitius	Comorbidity
A1 / Axxxxx	Xxxxx	Y	N	N
A1 / Axxxxx	Xxxxx	N	Y	N
A1 / Axxxxx	Xxxxx	Y	Y	Y
A1 / Axxxxx	Xxxxx	N	N	N

Listing 16.2.4.3: TB diagnosis and treatment history – ITT analysis set

Site/ Participant id	Treatment	Date of diagnosis	Start date of TB treatment	Date completed TB treatment	TB treatment	Start date	Stop date
A1 / Axxxxx	Xxxxx	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy	Ethambutol	ddmmmyyyy	ddmmmyyyy
					Isoniazid	ddmmmyyyy	ddmmmyyyy
					Pyrazinamide	ddmmmyyyy	ddmmmyyyy
					Rifampicin	ddmmmyyyy	ddmmmyyyy
A1 / Axxxxx	Xxxxx	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy	Ethambutol	ddmmmyyyy	ddmmmyyyy
					Isoniazid	ddmmmyyyy	ddmmmyyyy
					Pyrazinamide	ddmmmyyyy	ddmmmyyyy
					Rifampicin	ddmmmyyyy	ddmmmyyyy

Listing 16.2.4.4: Medical history – ITT analysis set

Site/ Participant id	Treatment	Hist. no.	Reported term	System organ class/ Preferred term	Ongoing (Y/N)	Start date	End date
A1 / Axxxxx	Xxxxx	X	xxxxxxx	Xxxxxx/ xxxxxxxxxxx	x	Ddmmmyyy	yyyy
A1 / Axxxxx	Xxxxx	x	Xxxxxx xxxxxxxx xxxxx	Xxxxxxxxxx/ xxxxxxxxxxxxx	x	mmmyyyy	

Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.4.5: Concomitant medication – ITT analysis set

Site/ Participant id	Treatment	Med. no.	ATC level 4 code/ ATC level 4 term	Generic drug name/ Reported drug name	Dose and unit/ Route/ Frequency	Start date/ End date	Ongoing (Y/N)	Indication/ Linked to
A1 / Axxxxx	Xxxxx	X	Xxxxxxx/ xxxxxxxxx	Xxxxxx/ xxxxxxxxxxx	xx mg/ xxxxxxxxx/ xxxxxxxx	Ddmmmyyyy	Y	Xxxxx/ xxxxxxxxxx
A1 / Axxxxx	Xxxxx	X	Xxxxxxx/ xxxxxxxxx	Xxxxxx/ xxxxxxxxxxx	xx mg/ xxxxxxxxx/ xxxxxxxx	Ddmmmyyyy/ ddmmmyyyy	N	Xxxxx/ xxxxxxxxxx
A1 / Axxxxx	Xxxxx	X	Xxxxxxx/ xxxxxxxxx	Xxxxxx/ xxxxxxxxxxx	xx mg/ xxxxxxxxx/ xxxxxxxx	Ddmmmyyyy/d dmmmyyyy	N	Xxxxx/ xxxxxxxxxx

Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.4.6: New TB treatment – ITT analysis set

< Layout similar to listing 16.2.4.5 >

Listing 16.2.4.7: Prohibited medication – ITT analysis set

Site/ Participant id	Treatment	Med. no.	ATC level 4 code/ ATC level 4 term	Generic drug name/ Reported drug name	Dose and unit/ Route/ Frequency	Start date/ End date	Start day / End day[1]	Ongoing (Y/N)	Indication/ Linked to
A1 / Axxxxx	Xxxxx	X	Xxxxxxx/ xxxxxxxxx	Xxxxxx/ xxxxxxxxxxx	xx mg/ xxxxxxxxx/ xxxxxxxx	ddmmmyyyy/ ddmmmyyyy	xx/xx	Y	Xxxxx/ xxxxxxxxxxx
A1 / Axxxxx	Xxxxx	X	Xxxxxxx/ xxxxxxxxx	Xxxxxx/ xxxxxxxxxxx	xx mg/ xxxxxxxxx/ xxxxxxxx	ddmmmyyyy/ ddmmmyyyy	Xx/xx	N	Xxxxx/ xxxxxxxxxxx
A1 / Axxxxx	Xxxxx	X	Xxxxxxx/ xxxxxxxxx	Xxxxxx/ xxxxxxxxxxx	xx mg/ xxxxxxxxx/ xxxxxxxx	ddmmmyyyy/ ddmmmyyyy	Xx/xx	N	Xxxxx/ xxxxxxxxxxx

1) Relative to1st vaccination
Trial: POR A-055
Program: <program>.sas – output: <output>.rtf – executed: DDMMMYYYY

Listing 16.2.5: Exposure – safety analysis set

Site/ Participant id	Treatment	Time from 1st to 2nd vaccination (days)	Vaccination date/time	Injection site	According to protocol	Injection site examined[1]	Any post dose AEs[1]	Vaccination performed/Reason not administered
A1 / Axxxxx	Xxxxx	Xx	ddmmmyyyy/hh:mm	xxxx xxx	xxx	xxx	Y	Y
			ddmmmyyyy/hh:mm	Xxxx xxx	xxx			N/Xxxxxxxx
A1 / Axxxxx	Xxxxx	Xx	ddmmmyyyy/hh:mm	xxxx xxx	xxx	xxx	N	Y
			ddmmmyyyy/hh:mm	xxxx xxx	xxx	xxx	N	Y

1) Within 50-70 min. after injection
Trial: POR A-055
Program: <program>.sas – output: <output>.rtf – executed: DDMMMYYYY

Listing 16.2.6.1: Efficacy response from day 70 – mITT analysis set

Site/ Participant id	Treatment	mITT/mITT2/PP/ ITT analysis set (Y/N)	Vaccination dates	Endpoint	Time to endpoint (days)	Analysis start/end date	Censored (Y/N)/ Event/censoring description
A1/ Axxxx	Xxxxx	Y/Y/Y/Y	ddmmmyyy / ddmmmyyy	Time from Day 70 to primary TB recurrence	xxx	ddmmmyyy / ddmmmyyy	N/ xxx
				Time from Day 70 to TB relapse	xx	ddmmmyyy / ddmmmyyy	N/ xxx
				Time from Day 70 to TB reinfection	xxx	ddmmmyyy / ddmmmyyy	Y/ xxx

Trial: POR A-055
Program: <program>.sas – output: <output>.rtf – executed: DDMMMYYYY

Listing 16.2.6.2: Efficacy response from day 0 and 30 – ITT analysis set

<Layout similar to listing 16.2.6.1>

Listing 16.2.6.3: Sputum collection – Participants with TB recurrence – culture of sputum – ITT analysis set

Site/ Participant id	Treatment	Visit	Sample no	Date	Reson for not collecting/ Other specification	Xpert MTB/RIF Ultra	Rifampicin resistance	Culture result	Recurrent TB
A1 / Axxxxx	Xxxxx	Visit 2	1	ddmmmyyy		xx	xx	xxxxxxxxxx	
			2	ddmmmyyy		xx	xx	xxxxxxxxxx	xx

Trial: POR A-055
Program: <program>.sas – output: <output>.rtf – executed: DDMMMYYYY

Listing 16.2.6.4: Sputum collection – Participants without TB recurrence – culture of sputum – ITT analysis set

< Layout similar to listing 16.2.4.2 >

Listing 16.2.6.5: TB strain – ITT analysis set

				WGS distance from Visit 1		tNGS lineage		Relapse /
Site/Participant id	Treatment	Visit	Date	Allele	SNP	Spoligo	SNP	Reinfection
A1 / Axxxxx	Xxxxx	Visit 1	ddmmmyyyy			x.x.x.x	xxxxxxx xxx	
		STB	ddmmmyyyy	xxx	xx	x.x.x	xxxxxx	xxxxxx
A1 / Axxxxx	Xxxxx	Visit 1	ddmmmyyyy			xxxx	xxxxx xxx	
		Visit 8	ddmmmyyyy	xxx	xxx	xxxx	xxxxx xxx	xxxxxx
A1 / Axxxxx	Xxxxx	Visit 1	ddmmmyyyy			xxxxx	xxxxx	
		STB	ddmmmyyyy	xxx	x	x.x.x	xxxxx	Xxxxxx

Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.6.6: Antigen specific cell mediated immune responses – WB ICS – Immunogenicity cohort

Site/ Participant id	Treatment	Immuno-genicity analysis set (Y/N)	Visit	Date	$CD4^+$ T-cells expressing any combination of IL-2, IFN-γ, TNF-α, or IL-17 (%)	$CD4^+$ T-cells co-expressing IL-2, IFN-γ and TNF-α (%)	$CD4^+$ T-cells co-expressing IL-2 and TNF-α (%)	$CD8^+$ T-cells expressing any combination of IL-2, IFN-γ, TNF-α, or IL-17 (%)
A1 / Axxxxx	Xxxxxx	Y	Visit 3 (Day 0)	ddmmmyyyy	xxx	xxx	xxx	xxx
			Visit 6 (Day 70)	ddmmmyyyy	xxx	xxx	xxx	xxx
A1 / Axxxxx	Xxxxxx	Y	Visit 3 (Day 0)	ddmmmyyyy	xxx	xxx	xxx	xxx
			Visit 6 (Day 70)	ddmmmyyyy	xxx	xxx	xxx	xxx
A1 / Axxxxx	Xxxxxx	Y	Visit 3 (Day 0)	ddmmmyyyy	xxx	xxx	xxx	xxx
			Visit 6 (Day 70)	ddmmmyyyy	xxx	xxx	xxx	xxx

Page 1 of x

Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.6.7: Anti-H56 IgG – Immunogenicity cohort

Site/ Participant id	Treatment	Immunogenicity analysis set (Y/N)	Visit	Date	Anti-H56 IgG (EU/mL)
A1 / Axxxxx	Xxxxx	X	Visit 3	ddmmmyyyy	xxx
			Visit 6	ddmmmyyyy	xxx

Page 1 of x

Trial: POR A-055
Program: <program>.sas - output: <output>.rtf - executed: DDMMMYYYY

Listing 16.2.7.1: Adverse events – Safety analysis set

Site/ Participant id	Treatment	AE no.	System organ class/ Preferred term/ Reported term	Start date End date	Duration (days)	Onset relative to 1st/ 2nd injection	Intensity/ Causality/ Outcome	Action taken/ AESI/Serious
Yyyy/ xxxxxx	Xxx	1	Xxxxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Ddmmmyyyy/ Ddmmmyyyy	xx	xx/ x .	xxxxx/ xxxxx/ xxx	xxxxxxx/x/x

Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.7.2: Solicited injection site reactions within 7 days after vaccination – Safety analysis set

Site/ Participant id	Treatment	AE no.	System organ class/ Preferred term/ Reported term	Start date End date	Duration (days)	Onset relative to 1st/ 2nd injection	Intensity/ Causality/ Outcome	Action taken/ Serious	Type/ Max diameter (mm)
Yyyy/ xxxxxx	H56:IC31	1	Xxxxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Ddmmmyyyy/ Ddmmmyyyy	xx	xx/ x .	xxxxx/ xxxxx/ xxx	xxxxxxx/ x	xxxxxxxx/ xx

Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.7.3: Solicited systemic reactions within 7 days from vaccination – Safety analysis set

Site/ Participant id	Treatment	AE no.	System organ class/ Preferred term/ Reported term	Start date End date	Duration (days)	Onset relative to 1st/ 2nd injection (days)	Intensity/ Causality/ Outcome	Action taken/ Serious	Max temp (°C)
Yyyy/ xxxxxx	xxx	1	Xxxxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Ddmmmyyyy/ Ddmmmyyyy	xx	x/xxx .	xxxxx/ xxxxx/ xxx	xxxxxx/x	xx.x
		2	Xxxxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Ddmmmyyyy/ Ddmmmyyyy	xx	x/xxx .	xxxxx/ xxxxx/ xxx	xxxxxx/x	
Yyyy/ xxxxxx	xxx	1	Xxxxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Ddmmmyyyy/ Ddmmmyyyy	xx	x/xxx .	xxxxx/ xxxxx/ xxx	xxxxxx/x	xx.x

Listing 16.2.7.4: Unsolicited adverse events within 14 days after vaccination – Safety analysis set

< Layout similar to listing 16.2.7.1 >

Listing 16.2.7.5: Adverse reactions – Safety analysis set

Site/ Participant id	Treatment	AE no.	System organ class/ Preferred term/ Reported term	Start date End date	Duration (days)	Onset relative to 1st/ 2nd injection (days)	Intensity/ outcome	Action taken/ AESI	SAR/ SUSAR
Yyyy/ xxxxxx	H56:IC31	1	Xxxxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Ddmmmyyyy/ Ddmmmyyyy	xx	x/ .	xxxxx/ xxx	xxxxxx/ x	X/ x

Page 1 of x

AESI: Adverse event of special interest, SAR: Serious adverse reaction, SUSAR: Suspected unexpected serious adverse reaction.
Solicited injection site reactions are considered related to the IMP regardless of the causality assessment by the investigator
Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.7.6: Adverse events of special interest – Safety analysis set

< Layout similar to listing 16.2.7.1 >

Listing 16.2.7.7: Serious adverse events – Safety analysis set

< Layout similar to listing 16.2.7.1 >

Listing 16.2.7.8: Adverse events leading to discontinuation of vaccination or withdrawal from trial – Safety analysis set

< Layout similar to listing 16.2.7.1 >

Listing 16.2.7.9: Fatal adverse events – Safety analysis set

< Layout similar to listing 16.2.7.1 >

Listing 16.2.7.10: Injection site reactions and systemic events occurring more than 14 days after vaccination – Safety analysis set

Site/ Participant id	Treatment	AE no.	System organ class/ Preferred term/ Reported term	Start date End date	Duration (days)	Onset relative to 1st/ 2nd injection	Intensity/ causality/ outcome	Action taken/ Serious	Type/ Max diameter (mm)/Max temp (°C)
Yyyy/ xxxxxx	xxx	1	Xxxxxxxxxxxxxxxxxxx/ Xxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Ddmmmyyyy/ Ddmmmyyyy	xx	xx/ x	xxxxx/ xxxxx/ xxx	xxxxxxx/ x	xxxxxxxx/ xx/xx.x

Injection site reactions are events marked as Injection site reactions in the eCRF.
Systemic events are events with preferred term pyrexia, arthralgia, myalgia, fatigue, headache, rash, chills, and nausea.
Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.7.11: Other non-serious adverse events occurring more than 14 days after vaccination – Safety analysis set

< Layout similar to listing 16.2.7.1 >

Listing 16.2.8.1: Vital signs – Safety analysis set

Site/ Participant id	Treatment	Date	Visit/Clin sign finding	Time point	Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)	Pulse rate (bpm)	Temperature (°C)
xxxx / xxxxxx	xxxxxx	ddmmmyyyy	Visit 2/Y		xxx	xx	xx	xx.x
		ddmmmyyyy	Visit 3/N	Pre-Dose	xxx	xx	xx	xx.x
				Post-Dose	xxx	xx	xx	xx.x
		ddmmmyyyy	Visit 4/N		xxx	xx	xx	xx.x
		ddmmmyyyy	Visit 5/Y	Pre-Dose	xxx	xx	xx	xx.x
				Post-Dose	xxx	xx	xx	xx.x
		ddmmmyyyy	Visit 6/N		xxx	xx	xx	xx.x

**: Measurement not used in summary tables/figures and analyses*
Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.8.2: Physical examination - Abnormal clinically significant findings – Safety analysis set

Site/ Participant id	Treatment	Date	Visit	Finding
xxxx / xxxxxx	xxxxxx	ddmmmyyyy	Visit 2	Xxxxxxxxxxx
		ddmmmyyyy	Visit 3	Xxxxxx
		ddmmmyyyy	Visit 5	Xxxxxxxxx xxxxx xxxxxxxxxxxxx

Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.8.3: Weight – Safety analysis set

Site/Participant id	Treatment	Date	Visit	Weight (kg)
xxxx / xxxxxx	xxxxxx	ddmmmyyyy	Visit 1	xx.x
		ddmmmyyyy	Visit 2	xx.x
		ddmmmyyyy	Visit 3	xx.x
		ddmmmyyyy	Visit 4	xx.x
		ddmmmyyyy	Visit 5	xx.x
		ddmmmyyyy	Unscheduled visit 5	xx.x*
		ddmmmyyyy	Visit 6	xx.x
		ddmmmyyyy	Visit 7	xx.x
xxxx / xxxxxx	xxxxxx	ddmmmyyyy	Visit 1	xx.x
		…		

**: Measurement not used in summary tables/figures and analyses*
Trial: POR A-055
Program: lst_vs.sas - output: lst_vs.rtf - executed: DDMMMYYYY

Listing 16.2.8.4: TB symptoms – Safety analysis set

Site/ Participant id	Treatment	Date	Visit	Signs and symptoms	Reason not performed
xxxx / xxxxxx	xxxxxx	ddmmmyyyy	Visit 4		Xxxxx xxxxxxxxxx
		ddmmmyyyy	Visit 6	Xxxx, xxx xx xxxxxx	

Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.9.1: Safety laboratory values – Biochemistry – Safety analysis set

Site/ Participant id	Treatment	Parameter (unit)	Reference range	Visit	Value	Reference range indicator	Clinically siginficant
xxxx / xxxxxx	xxxxxx	xxxxxxxx (xx)	xx - xx	Visit xxx	xx.x	Normal	N
				Visit xxx	xx.x*	High	Y
				Visit xxx	xx.x	Normal	N
				Visit xxx	xx.x	Normal	N
		xxxxxxxx (xx)	xx - xx	Visit xxx	xx.x	Normal	N

**: Measurement not used in summary tables/figures and analyses*
Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.9.2: Safety laboratory values – Haematology – Safety analysis set

< Layout similar to listing 16.2.9.1 >

Listing 16.2.9.3: Safety laboratory values – Urinalysis – Safety analysis set

Site/Participant id	Treatment	Parameter	Visit	Value	Clinically siginficant
xxxx / xxxxxx	xxxxxx	xxxxxxxx	Visit xxx	xxx	N
			Visit xxx	xxx*	Y
			Visit xxx	xxx	N
		xxxxxxxx	Visit xxx	xxx	N
			Visit xxx	xxx	N

**: Measurement not used in summary tables/figures and analyses*
Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.9.4: Clinically significant safety laboratory values – Safety analysis set

Site/Participant id	Treatment	Visit	Date	Specimen	Parameter (unit)	Value	Reference range
xxxx / xxxxxx	xxxxxx	Visit x	DDMMMYYYY	xxxx	xxxxxxxxxxxxx	xx	xx - xx
xxxx / xxxxxx	xxxxxx	Visit x	DDMMMYYYY	xxx	xxxxxxxxxxxxx	Xx*	xx - xx
xxxx / xxxxxx	xxxxxx	Visit x	DDMMMYYYY	xxxxx	xxxxxxxxxxxxx	xx	xx - xx

**: Measurement not used in summary tables/figures and analyses*
Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.9.5: Safety laboratory values – Pregnancy test – Safety analysis set

Site/Participant id	Treatment	Parameter	Visit	Value
xxxx / xxxxxx	xxxxxx	xxxxxxxx	Visit xxx	xxxx
			Visit xxx	xxxx
			Visit xxx	xxxx
			Visit xxx	xxxx
xxxx / xxxxxx	xxxxxx	xxxxxxxx	Visit xxx	xxxx
			Visit xxx	xxxx

Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.9.6: Pregnancies – Safety analysis set

Site/ Participant id	Treatment	Site notification date	Date of last IMP/ Date of pregnancy test	Estimated conception/ Delivery date	Number of previous pregnancies	Outcomes of previous pregnancies
xxxx / xxxxxx	xxxxxx	DDMMMYYYY	DDMMMYYYY/ DDMMMYYYY	DDMMMYYYY/ DDMMMYYYY	X	xxxxxx
xxxx / xxxxxx	xxxxxx	DDMMMYYYY	DDMMMYYYY/ DDMMMYYYY	DDMMMYYYY/ DDMMMYYYY	X	Xxxxxx
xxxx / xxxxxx	xxxxxx	DDMMMYYYY	DDMMMYYYY/ DDMMMYYYY	DDMMMYYYY/ DDMMMYYYY	X	xxxxxx

Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY

Listing 16.2.9.7: Pregnancy outcomes – Safety analysis set

Site/ Participant id	Treatment	Current pregnancy outcome	Sex/ Weight at birth (kg)	Mothers health	Childs health	Additional information
xxxx / xxxxxx	xxxxxx	Xxxxxxx	Xx/x.x	XXx	Xxxxxx	Xxxxx
xxxx / xxxxxx	xxxxxx	Xxxxx	Xx/x.x	XXx	Xxxxxx	Xxxxx
xxxx / xxxxxx	xxxxxx	Xxxxx	Xx/x.x	XXx	Xxxxxx	Xxxxx

Trial: POR A-055
Program: <program_name>.sas - output: <output_name>.rtf - executed: DDMMMYYYY